103d CONGRESS S. 1

AMENDMENT

In the House of Representatives, U. S.,

March 10, 1993.

Resolved, That the bill from the Senate (S. 1) entitled "An Act to amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes", do pass with the following

AMENDMENT:

Strike out all after the enacting clause, and insert:

- 1 SECTION 1. SHORT TITLE: TABLE OF CONTENTS.
- 2 (a) Short Title.—This Act may be cited as the "Na-
- 3 tional Institutes of Health Revitalization Act of 1993".
- 4 (b) Table of Contents for
- 5 this Act is as follows:
 - Sec. 1. Short title; table of contents.

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

Part I—Review of Proposals for Biomedical and Behavioral Research

Sec. 101. Establishment of certain provisions regarding research conducted or supported by National Institutes of Health.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

- Sec. 111. Establishment of authorities.
- Sec. 112. Purchase of human fetal tissue; solicitation or acceptance of tissue as directed donation for use in transplantation.
- Sec. 113. Nullification of moratorium.
- Sec. 114. Report by General Accounting Office on adequacy of requirements.

PART III—MISCELLANEOUS REPEALS

Sec. 121. Repeals.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I-Women and Minorities as Subjects in Clinical Research

- Sec. 131. Requirement of inclusion in research.
- Sec. 132. Peer review.
- Sec. 133. Applicability to current projects.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

Sec. 141. Establishment.

Part III—Office of Research on Minority Health

Sec. 151. Establishment.

Subtitle C—Research Integrity

- Sec. 161. Establishment of Office of Research Integrity.
- Sec. 162. Commission on Research Integrity.
- Sec. 163. Protection of whistleblowers.
- Sec. 164. Requirement of regulations regarding protection against financial conflicts of interest in certain projects of research.
- Sec. 165. Effective dates.

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

- Sec. 201. Health promotion research dissemination.
- Sec. 202. Programs for increased support regarding certain States and researchers.
- Sec. 203. Establishment of Office of Behavioral Research.
- Sec. 204. Children's vaccine initiative.
- Sec. 205. Plan for use of animals in research.
- Sec. 206. Increased participation of women and disadvantaged individuals in fields of biomedical and behavioral research.
- Sec. 207. Requirements regarding surveys of sexual behavior.
- Sec. 208. Discretionary fund of Director of National Institutes of Health.
- Sec. 209. Establishment of Office of Alternative Medicine.
- Sec. 210. Miscellaneous provisions.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

- Sec. 301. Appointment and authority of Directors of national research institutes.
- Sec. 302. Program of research on osteoporosis, Paget's disease, and related disorders.
- Sec. 303. Establishment of interagency program for trauma research.

TITLE IV—NATIONAL CANCER INSTITUTE

- Sec. 401. Expansion and intensification of activities regarding breast cancer.
- Sec. 402. Expansion and intensification of activities regarding prostate cancer.
- Sec. 403. Authorization of appropriations.
- Sec. 404. Study of environmental and other risks contributing to incidence of breast cancer.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Sec. 501. Education and training.

- Sec. 502. Centers for the study of pediatric cardiovascular diseases.
- Sec. 503. National Center on Sleep Disorders.
- Sec. 504. Authorization of appropriations.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Sec. 601. Provisions regarding nutritional disorders.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Sec. 701. Juvenile arthritis.

TITLE VIII—NATIONAL INSTITUTE ON AGING

- Sec. 801. Alzheimer's disease registry.
- Sec. 802. Aging processes regarding women.
- Sec. 803. Authorization of appropriations.
- Sec. 804. Conforming amendment.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

- Sec. 901. Tropical diseases.
- Sec. 902. Chronic fatigue syndrome.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

- Subtitle A—Research Centers With Respect to Contraception and Research Centers With Respect to Infertility
- Sec. 1001. Grants and contracts for research centers.
- Sec. 1002. Loan repayment program for research with respect to contraception and infertility.

Subtitle B—Program Regarding Obstetrics and Gynecology

Sec. 1011. Establishment of program.

Subtitle C—Child Health Research Centers

Sec. 1021. Establishment of centers.

Subtitle D—Study Regarding Adolescent Health

Sec. 1031. Prospective longitudinal study.

TITLE XI—NATIONAL EYE INSTITUTE

Sec. 1101. Clinical research on diabetes eye care.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Sec. 1201. Research on multiple sclerosis.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Sec. 1301. Applied Toxicological Research and Testing Program.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

Sec. 1401. Additional authorities.

Sec. 1402. Authorization of appropriations.

Subtitle B—Financial Assistance

Sec. 1411. Establishment of program of grants for development of education technologies.

Subtitle C—National Information Center on Health Services Research and Health Care Technology

Sec. 1421. Establishment of Center.

Sec. 1422. Conforming provisions.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

Sec. 1501. Redesignation of Division as National Center for Research Resources.

Sec. 1502. Biomedical and behavioral research facilities.

Sec. 1503. Construction program for national primate research center.

Subtitle B—National Center for Nursing Research

Sec. 1511. Redesignation of National Center for Nursing Research as National Institute of Nursing Research.

Sec. 1512. Study on adequacy of number of nurses.

Subtitle C—National Center for Human Genome Research

Sec. 1521. Purpose of Center.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

Sec. 1601. Requirement regarding women and individuals from disadvantaged backgrounds.

Subtitle B—Acquired Immune Deficiency Syndrome

Sec. 1611. Loan repayment program.

Subtitle C—Loan Repayment for Research Generally

Sec. 1621. Establishment of program.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by National Institutes of Health

Sec. 1631. Establishment of programs.

Sec. 1632. Funding.

Subtitle E—Funding for Awards and Training Generally

Sec. 1641. Authorization of appropriations.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

Sec. 1701. Date certain for appointment of Board members.

Sec. 1702. Miscellaneous provisions.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

Subtitle A—Office of AIDS Research

Sec. 1801. Establishment of Office.

Sec. 1802. Establishment of emergency discretionary fund.

Sec. 1803. General provisions.

Subtitle B—Certain Programs

Sec. 1811. Revision and extension of certain programs.

TITLE XIX—STUDIES

Sec. 1901. Acquired immune deficiency syndrome.

Sec. 1902. Malnutrition in the elderly.

Sec. 1903. Research activities on chronic fatigue syndrome.

Sec. 1904. Report on medical uses of biological agents in development of defenses against biological warfare.

Sec. 1905. Personnel study of recruitment, retention and turnover.

Sec. 1906. Procurement.

Sec. 1907. Chronic pain conditions.

Sec. 1908. Back injuries.

TITLE XX—MISCELLANEOUS PROVISIONS

Sec. 2001. Designation of Senior Biomedical Research Service in honor of Silvio O. Conte; limitation on number of members.

Sec. 2002. Master plan for physical infrastructure for research.

Sec. 2003. Certain authorization of appropriations.

Sec. 2004. Buy-American provisions.

Sec. 2005. Prohibition against further funding for Project Aries.

TITLE XXI—EFFECTIVE DATES

Sec. 2101. Effective dates.

1	TITLE I—GENERAL PROVISIONS
2	REGARDING TITLE IV OF PUB-
3	LIC HEALTH SERVICE ACT
4	Subtitle A—Research Freedom
5	PART I—REVIEW OF PROPOSALS FOR
6	BIOMEDICAL AND BEHAVIORAL RESEARCH
7	SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS RE-
8	GARDING RESEARCH CONDUCTED OR SUP-
9	PORTED BY NATIONAL INSTITUTES OF
10	HEALTH.
11	Part G of title IV of the Public Health Service Act
12	(42 U.S.C. 289 et seq.) is amended by inserting after section
13	492 the following new section:
14	"CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL
15	OF PROPOSALS FOR RESEARCH
16	"Sec. 492A. (a) Review as Precondition to Re-
17	SEARCH.—
18	"(1) Protection of human research sub-
19	JECTS.—
20	"(A) In the case of any application submit-
21	ted to the Secretary for financial assistance to
22	conduct research, the Secretary may not approve
23	or fund any application that is subject to review
24	under section 491(a) by an Institutional Review
25	Board unless the application has undergone re-

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view in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

- "(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.
- "(2) PEER REVIEW.—In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to technical and scientific peer review under section 492(a) unless the application has undergone peer review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review.

22 "(b) ETHICAL REVIEW OF RESEARCH.—

"(1) Procedures regarding withholding of funds.—If research has been recommended for approval for purposes of subsection (a), the Secretary

1	may not withhold funding for the research on ethical
2	grounds unless—
3	"(A) the Secretary convenes an advisory
4	board in accordance with paragraph (4) to study
5	the ethical implications of the research; and
6	"(B)(i) the majority of the advisory board
7	recommends that, on ethical grounds, the Sec-
8	retary withhold funds for the research; or
9	(ii) the majority of such board recommends
10	that the Secretary not withhold funds for the re-
11	search on ethical grounds, but the Secretary
12	finds, on the basis of the report submitted under
13	paragraph $(4)(B)(ii)$, that the recommendation
14	is arbitrary and capricious.
15	"(2) Applicability.—The limitation established
16	in paragraph (1) regarding the authority to withhold
17	funds on ethical grounds shall apply without regard
18	to whether the withholding of funds on such grounds
19	is characterized as a disapproval, a moratorium, a
20	prohibition, or other description.
21	"(3) Preliminary matters regarding use of
22	PROCEDURES.—
23	"(A) If the Secretary makes a determina-
24	tion that an advisory board should be convened
25	for purposes of paragraph (1), the Secretary

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1	shall, through a statement published in the Fed-
2	eral Register, announce the intention of the Sec-
3	retary to convene such a board.
4	"(B) A statement issued under subpara-
5	graph (A) shall include a request that interested
6	individuals submit to the Secretary recommenda-
7	tions specifying the particular individuals who
8	should be appointed to the advisory board in-
9	volved. The Secretary shall consider such rec-
10	ommendations in making appointments to the
11	board.
12	"(C) The Secretary may not make appoint
13	ments to an advisory board under paragraph (1)
14	until the expiration of the 30-day period begin-
15	ning on the date on which the statement required
16	in subparagraph (A) is made with respect to the
17	board.
18	"(4) Ethics advisory boards.—
19	"(A) Any advisory board convened for pur-

"(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (hereafter in this paragraph referred to as an 'ethics board').

"(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of bio-

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medical or behavioral research with respect to which the board has been convened.

on which the statement required in paragraph (3)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

"(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

1	"(i) no fewer than 1 shall be an attor-
2	ney;
3	"(ii) no fewer than 1 shall be an
4	ethicist;
5	"(iii) no fewer than 1 shall be a prac-
6	ticing physician;
7	"(iv) no fewer than 1 shall be a theolo-
8	gian; and
9	"(v) no fewer than one-third, and no
10	more than one-half, shall be scientists with
11	substantial accomplishments in biomedical
12	or behavioral research.
13	"(D) The term of service as a member of an
14	ethics board shall be for the life of the board. If
15	such a member does not serve the full term of
16	such service, the individual appointed to fill the
17	resulting vacancy shall be appointed for the re-
18	mainder of the term of the predecessor of the in-
19	dividual.
20	"(E) A member of an ethics board shall be
21	subject to removal from the board by the Sec-
22	retary for neglect of duty or malfeasance or for
23	other good cause shown.

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1	"(F) The Secretary shall designate an indi-
2	vidual from among the members of an ethics
3	board to serve as the chair of the board.
4	"(G) In carrying out subparagraph (B)(i)
5	with respect to a project of research, an ethics
6	board shall conduct inquiries and hold public
7	hearings.
8	"(H) In carrying out subparagraph (B)(i)
9	with respect to a project of research, an ethics
10	board shall have access to all relevant informa-
11	tion possessed by the Department of Health and
12	Human Services, or available to the Secretary
13	from other agencies.
14	"(I) Members of an ethics board shall re-
15	ceive compensation for each day engaged in car-
16	rying out the duties of the board, including time
17	engaged in traveling for purposes of such duties.
18	Such compensation may not be provided in an
19	amount in excess of the maximum rate of basic
20	pay payable for GS-18 of the General Schedule.
21	"(J) The Secretary, acting through the Di-
22	rector of the National Institutes of Health, shall
23	provide to each ethics board reasonable staff and

assistance to carry out the duties of the board.

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1	"(K) An ethics board shall terminate 30
2	days after the date on which the report required
3	in subparagraph (B)(ii) is submitted to the Sec-
4	retary and the congressional committees specified
5	in such subparagraph.''.
6	PART II—RESEARCH ON TRANSPLANTATION OF
7	FETAL TISSUE
8	SEC. 111. ESTABLISHMENT OF AUTHORITIES.
9	Part G of title IV of the Public Health Service Act
10	(42 U.S.C. 289 et seq.) is amended by inserting after section
11	498 the following new section:
12	"RESEARCH ON TRANSPLANTATION OF FETAL TISSUE
13	"Sec. 498A. (a) Establishment of Program.—
14	"(1) In General.—The Secretary may conduct
15	or support research on the transplantation of human
16	fetal tissue for therapeutic purposes.
17	"(2) Source of tissue.—Human fetal tissue
18	may be used in research carried out under paragraph
19	(1) regardless of whether the tissue is obtained pursu-
20	ant to a spontaneous or induced abortion or pursuant
21	to a stillbirth.
22	"(b) Informed Consent of Donor.—
23	"(1) In GENERAL.—In research carried out
24	under subsection (a), human fetal tissue may be used
2.5	only if the woman providing the tissue makes a state-

1	ment, made in writing and signed by the woman, de-
2	claring that—
3	"(A) the woman donates the fetal tissue for
4	use in research described in subsection (a);
5	"(B) the donation is made without any re-
6	striction regarding the identity of individuals
7	who may be the recipients of transplantations of
8	the tissue; and
9	"(C) the woman has not been informed of
10	the identity of any such individuals.
11	"(2) Additional statement.—In research car-
12	ried out under subsection (a), human fetal tissue may
13	be used only if the attending physician with respect
14	to obtaining the tissue from the woman involved
15	makes a statement, made in writing and signed by
16	the physician, declaring that—
17	"(A) in the case of tissue obtained pursuant
18	to an induced abortion—
19	"(i) the consent of the woman for the
20	abortion was obtained prior to requesting or
21	obtaining consent for a donation of the tis-
22	sue for use in such research;
23	"(ii) no alteration of the timing, meth-
24	od, or procedures used to terminate the

1	pregnancy was made solely for the purposes
2	of obtaining the tissue; and
3	"(iii) the abortion was performed in
4	accordance with applicable State law;
5	"(B) the tissue has been donated by the
6	woman in accordance with paragraph (1); and
7	"(C) full disclosure has been provided to the
8	woman with regard to—
9	"(i) such physician's interest, if any,
10	in the research to be conducted with the tis-
11	sue; and
12	"(ii) any known medical risks to the
13	woman or risks to her privacy that might
14	be associated with the donation of the tissue
15	and that are in addition to risks of such
16	type that are associated with the woman's
17	medical care.
18	"(c) Informed Consent of Researcher and
19	Donee.—In research carried out under subsection (a),
20	human fetal tissue may be used only if the individual with
21	the principal responsibility for conducting the research in-
22	volved makes a statement, made in writing and signed by
23	the individual, declaring that the individual—
24	"(1) is aware that—
25	"(A) the tissue is human fetal tissue;

1	"(B) the tissue may have been obtained pur-
2	suant to a spontaneous or induced abortion or
3	pursuant to a stillbirth; and
4	"(C) the tissue was donated for research
5	purposes;
6	"(2) has provided such information to other in-
7	dividuals with responsibilities regarding the research;
8	"(3) will require, prior to obtaining the consent
9	of an individual to be a recipient of a transplan-
10	tation of the tissue, written acknowledgment of receipt
11	of such information by such recipient; and
12	"(4) has had no part in any decisions as to the
13	timing, method, or procedures used to terminate the
14	pregnancy made solely for the purposes of the re-
15	search.
16	"(d) Availability of Statements for Audit.—
17	"(1) IN GENERAL.—In research carried out
18	under subsection (a), human fetal tissue may be used
19	only if the head of the agency or other entity conduct-
20	ing the research involved certifies to the Secretary
21	that the statements required under subsections (b) (2)
22	and (c) will be available for audit by the Secretary.
23	"(2) Confidentiality of Audit.—Any audit
24	conducted by the Secretary pursuant to paragraph (1)
25	shall be conducted in a confidential manner to protect

1	the privacy rights of the individuals and entities in-
2	volved in such research, including such individuals
3	and entities involved in the donation, transfer, re-
4	ceipt, or transplantation of human fetal tissue. With
5	respect to any material or information obtained pur-
6	suant to such audit, the Secretary shall—
7	"(A) use such material or information only
8	for the purposes of verifying compliance with the
9	requirements of this section;
10	"(B) not disclose or publish such material
11	or information, except where required by Federal
12	law, in which case such material or information
13	shall be coded in a manner such that the identi-
14	ties of such individuals and entities are pro-
15	tected; and
16	"(C) not maintain such material or infor-
17	mation after completion of such audit, except
18	where necessary for the purposes of such audit.
19	"(e) Applicability of State and Local Law.—
20	"(1) Research conducted by recipients of
21	ASSISTANCE.—The Secretary may not provide sup-
22	port for research under subsection (a) unless the ap-
23	plicant for the financial assistance involved agrees to
24	conduct the research in accordance with applicable
25	State law.

1	"(2) Research conducted by secretary.—
2	The Secretary may conduct research under subsection
3	(a) only in accordance with applicable State and
4	local law.
5	"(f) Report.—The Secretary shall annually submit to
6	the Committee on Energy and Commerce of the House of
7	Representatives, and to the Committee on Labor and
8	Human Resources of the Senate, a report describing the ac-
9	tivities carried out under this section during the preceding
10	fiscal year, including a description of whether and to what
11	extent research under subsection (a) has been conducted in
12	accordance with this section.
13	"(g) Definition.—For purposes of this section, the
14	term 'human fetal tissue' means tissue or cells obtained
15	from a dead human embryo or fetus after a spontaneous
16	or induced abortion, or after a stillbirth.".
17	SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-
18	TION OR ACCEPTANCE OF TISSUE AS DI-
19	RECTED DONATION FOR USE IN TRANSPLAN-
20	TATION.
21	Part G of title IV of the Public Health Service Act,
22	as amended by section 111 of this Act, is amended by insert-
23	ing after section 498A the following new section:
) /	
24	"PROHIBITIONS REGARDING HUMAN FETAL TISSUE
25	"PROHIBITIONS REGARDING HUMAN FETAL TISSUE" "SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be

1	otherwise transfer any human fetal tissue for valuable con-
2	sideration if the transfer affects interstate commerce.
3	"(b) Solicitation or Acceptance of Tissue as Di-
4	RECTED DONATION FOR USE IN TRANSPLANTATION.—It
5	shall be unlawful for any person to solicit or knowingly
6	acquire, receive, or accept a donation of human fetal tissue
7	for the purpose of transplantation of such tissue into an-
8	other person if the donation affects interstate commerce, the
9	tissue will be or is obtained pursuant to an induced abor-
10	tion, and—
11	"(1) the donation will be or is made pursuant to
12	a promise to the donating individual that the donated
13	tissue will be transplanted into a recipient specified
14	by such individual;
15	"(2) the donated tissue will be transplanted into
16	a relative of the donating individual; or
17	"(3) the person who solicits or knowingly ac-
18	quires, receives, or accepts the donation has provided
19	valuable consideration for the costs associated with
20	such abortion.
21	"(c) Criminal Penalties for Violations.—
22	"(1) In GENERAL.—Any person who violates sub-
23	section (a) or (b) shall be fined in accordance with
24	title 18, United States Code, subject to paragraph (2),
25	or imprisoned for not more than 10 years, or both.

1	"(2) Penalties applicable to persons re-
2	CEIVING CONSIDERATION.—With respect to the impo-
3	sition of a fine under paragraph (1), if the person in-
4	volved violates subsection (a) or (b)(3), a fine shall be
5	imposed in an amount not less than twice the amount
6	of the valuable consideration received.
7	"(d) Definitions.—For purposes of this section:
8	"(1) The term 'human fetal tissue' has the mean-
9	ing given such term in section 498A(f).
10	"(2) The term 'interstate commerce' has the
11	meaning given such term in section 201(b) of the Fed-
12	eral Food, Drug, and Cosmetic Act.
13	"(3) The term 'valuable consideration' does not
14	include reasonable payments associated with the
15	transportation, implantation, processing, preserva-
16	tion, quality control, or storage of human fetal
17	tissue. ''.
18	SEC. 113. NULLIFICATION OF MORATORIUM.
19	(a) In General.—Except as provided in subsection
20	(c), no official of the executive branch may impose a policy
21	that the Department of Health and Human Services is pro-
22	hibited from conducting or supporting any research on the
23	transplantation of human fetal tissue for therapeutic pur-
24	poses. Such research shall be carried out in accordance with
25	section 498A of the Public Health Service Act (as added

1	by section 111 of this Act), without regard to any such pol-
2	icy that may have been in effect prior to the date of the
3	enactment of this Act.
4	(b) Prohibition Against Withholding of Funds
5	IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—
6	(1) In general.—In the case of any proposal
7	for research on the transplantation of human fetal tis-
8	sue for therapeutic purposes, the Secretary of Health
9	and Human Services may not withhold funds for the
10	research if—
11	(A) the research has been approved for pur-
12	poses of section 492A(a) of the Public Health
13	Service Act (as added by section 101 of this Act),
14	(B) the research will be carried out in ac-
15	cordance with section 498A of such Act (as added
16	by section 111 of this Act); and
17	(C) there are reasonable assurances that the
18	research will not utilize any human fetal tissue
19	that has been obtained in violation of section
20	498B(a) of such Act (as added by section 112 of
21	this Act).
22	(2) Standing approval regarding ethical
23	STATUS.—In the case of any proposal for research or
24	the transplantation of human fetal tissue for thera-
25	peutic purposes, the issuance in December 1988 of the

1	Report of the Human Fetal Tissue Transplantation
2	Research Panel shall be deemed to be a report—
3	(A) issued by an ethics advisory board pur-
4	suant to section 492A(b)(4)(B)(ii) of the Public
5	Health Service Act (as added by section 101 of
6	this Act); and
7	(B) finding, on a basis that is neither arbi-
8	trary nor capricious, that there are no ethical
9	grounds for withholding funds for the research.
10	(c) Authority for Withholding Funds From Re-
11	SEARCH.—In the case of any research on the transplan-
12	tation of human fetal tissue for therapeutic purposes, the
13	Secretary of Health and Human Services may withhold
14	funds for the research if any of the conditions specified in
15	any of subparagraphs (A) through (C) of subsection (b)(1)
16	are not met with respect to the research.
17	(d) Definition.—For purposes of this section, the
18	term "human fetal tissue" has the meaning given such term
19	in section 498A(f) of the Public Health Service Act (as
20	added by section 111 of this Act).
21	SEC. 114. REPORT BY GENERAL ACCOUNTING OFFICE ON
22	ADEQUACY OF REQUIREMENTS.
23	(a) In General.—With respect to research on the
24	transplantation of human fetal tissue for therapeutic pur-

1	poses, the Comptroller General of the United States shall
2	conduct an audit for the purpose of determining—
3	(1) whether and to what extent such research
4	conducted or supported by the Secretary of Health
5	and Human Services has been conducted in accord-
6	ance with section 498A of the Public Health Service
7	Act (as added by section 111 of this Act); and
8	(2) whether and to what extent there have been
9	violations of section 498B of such Act (as added by
10	section 112 of this Act).
11	(b) Report.—Not later than May 19, 1995, the Comp-
12	troller General of the United States shall complete the audit
13	required in subsection (a) and submit to the Committee on
14	Energy and Commerce of the House of Representatives, and
15	to the Committee on Labor and Human Resources of the
16	Senate, a report describing the findings made pursuant to
17	the audit.
18	PART III—MISCELLANEOUS REPEALS
19	SEC. 121. REPEALS.
20	(a) Certain Biomedical Ethics Board.—Title III
21	of the Public Health Service Act (42 U.S.C. 241 et seq.)
22	is amended by striking part J.
23	(b) Other Repeals.—Part G of title IV of the Public
24	Health Service Act (42 U.S.C. 289 et seq.) is amended—
25	(1) in section 498, by striking subsection (c); and

1	(2) by striking section 499; and
2	(3) by redesignating section 499A as section 499.
3	(c) Nullification of Certain Provisions.—The
4	provisions of Executive Order 12806 (57 Fed. Reg. 21589
5	(May 21, 1992)) shall not have any legal effect. The provi-
6	sions of section 204(d) of part 46 of title 45 of the Code
7	of Federal Regulations (45 CFR 46.204(d)) shall not have
8	any legal effect.
9	Subtitle B—Clinical Research Eq-
10	uity Regarding Women and Mi-
11	norities and the second
12	PART I—WOMEN AND MINORITIES AS SUBJECTS
13	IN CLINICAL RESEARCH
14	SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.
15	Part G of title IV of the Public Health Service Act,
16	as amended by section 101 of this Act, is amended by insert-
17	ing after section 492A the following new section:
18	"INCLUSION OF WOMEN AND MINORITIES IN CLINICAL
19	RESEARCH
20	"Sec. 492B. (a) Requirement of Inclusion.—
21	"(1) In General.—In conducting or supporting
22	clinical research for purposes of this title, the Director
23	of NIH shall, subject to subsection (b), ensure that—
24	"(A) women are included as subjects in each
25	project of such research; and

1	"(B) members of minority groups are in-
2	cluded as subjects in such research.
3	"(2) Outreach regarding participation as
4	SUBJECTS.—The Director of NIH, in consultation
5	with the Director of the Office of Research on Wom-
6	en's Health and the Director of the Office of Research
7	on Minority Health, shall conduct or support out-
8	reach programs for the recruitment of women and
9	members of minority groups as subjects in projects of
10	clinical research.
11	"(b) Inapplicability of Requirement.—The re-
12	quirement established in subsection (a) regarding women
13	and members of minority groups shall not apply to a
14	project of clinical research if the inclusion, as subjects in
15	the project, of women and members of minority groups, re-
16	spectively—
17	"(1) is inappropriate with respect to the health
18	of the subjects;
19	"(2) is inappropriate with respect to the purpose
20	of the research; or
21	"(3) is inappropriate under such other cir-
22	cumstances as the Director of NIH may designate.
23	"(c) Design of Clinical Trials.—In the case of any
24	clinical trial in which women or members of minority
25	groups will under subsection (a) be included as subjects, the

1	Director of NIH shall ensure that the trial is designed and
2	carried out in a manner sufficient to provide for a valid
3	analysis of whether the variables being studied in the trial
4	affect women or members of minority groups, as the case
5	may be, differently than other subjects in the trial.
6	"(d) Guidelines.—
7	"(1) In General.—Subject to paragraph (2), the
8	Director of NIH, in consultation with the Director of
9	the Office of Research on Women's Health and the Di-
10	rector of the Office of Research on Minority Health,
11	shall establish guidelines regarding the requirements
12	of this section. The guidelines shall include guidelines
13	regarding—
14	"(A) the circumstances under which the in-
15	clusion of women and minorities as subjects in
16	projects of clinical research is inappropriate for
17	purposes of subsection (b);
18	"(B) the manner in which clinical trials
19	are required to be designed and carried out for
20	purposes of subsection (c); and
21	"(C) the operation of outreach programs
22	under subsection (a).
23	"(2) Certain provisions.—With respect to the
24	circumstances under which the inclusion of women or
25	members of minority groups (as the case may be) as

subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

"(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

"(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or will be obtained through other means that provide data of comparable quality.

"(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

1	"(i) the effects that the variables to be
2	studied in the trial have on women or mem-
3	bers of minority groups, respectively; and
4	"(ii) the effects that the variables have
5	on the individuals who would serve as sub-
6	jects in the trial in the event that such in-
7	clusion were not required.
8	"(e) Date Certain for Guidelines; Applicabil-
9	ITY.—
10	"(1) Date certain.—The guidelines required in
11	subsection (d) shall be established and published in
12	the Federal Register not later than 180 days after the
13	date of the enactment of the National Institutes of
14	Health Revitalization Act of 1993.
15	"(2) Applicability.—For fiscal year 1995 and
16	subsequent fiscal years, the Director of NIH may not
17	approve any proposal of clinical research to be con-
18	ducted or supported by any agency of the National
19	Institutes of Health unless the proposal specifies the
20	manner in which the research will comply with this
21	section.
22	"(f) Reports by Advisory Councils.—The advisory
23	council of each national research institute shall annually
24	submit to the Director of NIH and the Director of the insti-

- 1 tute involved a report describing the manner in which the
- 2 agency has complied with this section.
- 3 "(g) Definitions.—For purposes of this section:
- 4 "(1) The term 'project of clinical research' in-
- 5 cludes a clinical trial.
- 6 "(2) The term 'minority group' includes sub-
- 7 populations of minority groups. The Director of NIH
- 8 shall, through the guidelines established under sub-
- 9 section (d), define the terms 'minority group' and
- 10 'subpopulation' for purposes of the preceding sen-
- 11 tence.".
- 12 **SEC. 132. PEER REVIEW.**
- 13 Section 492 of the Public Health Service Act (42
- 14 U.S.C. 289a) is amended by adding at the end the following
- 15 new subsection:
- 16 "(c)(1) In technical and scientific peer review under
- 17 this section of proposals for clinical research, the consider-
- 18 ation of any such proposal (including the initial consider-
- 19 ation) shall, except as provided in paragraph (2), include
- 20 an evaluation of the technical and scientific merit of the
- 21 proposal regarding compliance with section 492B.
- 22 "(2) Paragraph (1) shall not apply to any proposal
- 23 for clinical research that, pursuant to subsection (b) of sec-
- 24 tion 492B, is not subject to the requirement of subsection
- 25 (a) of such section regarding the inclusion of women and

1	members of minority groups as subjects in clinical re-
2	search.''.
3	SEC. 133. APPLICABILITY TO CURRENT PROJECTS.
4	Section 492B of the Public Health Service Act, as
5	added by section 131 of this Act, shall not apply with re-
6	spect to projects of clinical research for which initial fund-
7	ing was provided prior to the date of the enactment of this
8	Act. With respect to the inclusion of women and minorities
9	as subjects in clinical research conducted or supported by
10	the National Institutes of Health, any policies of the Sec-
11	retary of Health and Human Services regarding such inclu-
12	sion that are in effect on the day before the date of the enact-
13	ment of this Act shall continue to apply to the projects re-
14	ferred to in the preceding sentence.
15	PART II—OFFICE OF RESEARCH ON WOMEN'S
16	HEALTH
17	SEC. 141. ESTABLISHMENT.
18	(a) In General.—Title IV of the Public Health Serv-
19	ice Act, as amended by the preceding provisions of this title,
20	is amended—
21	(1) by redesignating section 486 as section 485A;
22	(2) by redesignating parts F through H as parts
23	G through I, respectively; and
24	(3) by inserting after part E the following new
25	part:

1	"Part F—Research on Women's Health
2	"SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.
3	"(a) Establishment.—There is established within
4	the Office of the Director of NIH an office to be known as
5	the Office of Research on Women's Health (in this part re-
6	ferred to as the 'Office'). The Office shall be headed by a
7	director, who shall be appointed by the Director of NIH.
8	"(b) Purpose.—The Director of the Office shall—
9	"(1) identify projects of research on women's
10	health that should be conducted or supported by the
11	national research institutes;
12	"(2) identify multidisciplinary research relating
13	to research on women's health that should be so con-
14	ducted or supported;
15	"(3) carry out paragraphs (1) and (2) with re-
16	spect to the aging process in women, with priority
17	given to menopause;
18	"(4) promote coordination and collaboration
19	among entities conducting research identified under
20	any of paragraphs (1) through (3);
21	"(5) encourage the conduct of such research by
22	entities receiving funds from the national research in-
23	stitutes;
24	"(6) recommend an agenda for conducting and
25	supporting such research:

1	"(7) promote the sufficient allocation of the re-
2	sources of the national research institutes for conduct-
3	ing and supporting such research;
4	"(8) assist in the administration of section 492E
5	with respect to the inclusion of women as subjects in
6	clinical research; and
7	"(9) prepare the report required in section 486B.
8	"(c) Coordinating Committee.—
9	"(1) In carrying out subsection (b), the Director
10	of the Office shall establish a committee to be known
11	as the Coordinating Committee on Research on Wom-
12	en's Health (hereafter in this subsection referred to as
13	the 'Coordinating Committee').
14	"(2) The Coordinating Committee shall be com-
15	posed of the Directors of the national research insti-
16	tutes (or the designees of the Directors).
17	"(3) The Director of the Office shall serve as the
18	chair of the Coordinating Committee.
19	"(4) With respect to research on women's health,
20	the Coordinating Committee shall assist the Director
21	of the Office in—
22	"(A) identifying the need for such research,
23	and making an estimate each fiscal year of the
24	funds needed to adequately support the research

1	"(B) identifying needs regarding the coordi-
2	nation of research activities, including intra-
3	mural and extramural multidisciplinary activi-
4	ties;
5	"(C) supporting the development of meth-
6	odologies to determine the circumstances in
7	which obtaining data specific to women (includ-
8	ing data relating to the age of women and the
9	membership of women in ethnic or racial
10	groups) is an appropriate function of clinical
11	trials of treatments and therapies;
12	"(D) supporting the development and ex-
13	pansion of clinical trials of treatments and
14	therapies for which obtaining such data has been
15	determined to be an appropriate function; and
16	"(E) encouraging the national research in-
17	stitutes to conduct and support such research, in-
18	cluding such clinical trials.
19	"(d) Advisory Committee.—
20	"(1) In carrying out subsection (b), the Director
21	of the Office shall establish an advisory committee to
22	be known as the Advisory Committee on Research on
23	Women's Health (hereafter in this subsection referred
24	to as the 'Advisory Committee').

1	"(2) The Advisory Committee shall be composed
2	of no fewer than 12, and not more than 18 individ-
3	uals, who are not officers or employees of the Federal
4	Government. The Director of the Office shall make ap-
5	pointments to the Advisory Committee from among
6	physicians, practitioners, scientists, and other health
7	professionals, whose clinical practice, research spe-
8	cialization, or professional expertise includes a sig-
9	nificant focus on research on women's health. A ma-
10	jority of the members of the Advisory Committee shall
11	be women.
12	"(3) The Director of the Office shall serve as the
13	chair of the Advisory Committee.
14	"(4) The Advisory Committee shall—
15	"(A) advise the Director of the Office on ap-
16	propriate research activities to be undertaken by
17	the national research institutes with respect to—
18	"(i) research on women's health;
19	"(ii) research on gender differences in
20	clinical drug trials, including responses to
21	pharmacological drugs;
22	"(iii) research on gender differences in
23	disease etiology, course, and treatment;

1	"(iv) research on obstetrical and gyne-
2	cological health conditions, diseases, and
3	treatments; and
4	"(v) research on women's health condi-
5	tions which require a multidisciplinary ap-
6	proach;
7	"(B) report to the Director of the Office on
8	such research;
9	"(C) provide recommendations to such Di-
10	rector regarding activities of the Office (includ-
11	ing recommendations on the development of the
12	methodologies $described$ in $subsection$ $(c)(4)(C)$
13	and recommendations on priorities in carrying
14	out research described in subparagraph (A)); and
15	"(D) assist in monitoring compliance with
16	section 492B regarding the inclusion of women
17	in clinical research.
18	"(5)(A) The Advisory Committee shall prepare a
19	biennial report describing the activities of the Com-
20	mittee, including findings made by the Committee re-
21	garding—
22	"(i) compliance with section 492B;
23	"(ii) the extent of expenditures made for re-
24	search on women's health by the agencies of the
25	National Institutes of Health; and

1	"(iii) the level of funding needed for such
2	research.
3	"(B) The report required in subparagraph (A)
4	shall be submitted to the Director of NIH for inclu-
5	sion in the report required in section 403.
6	"(e) Representation of Women Among Research-
7	ERS.—The Secretary, acting through the Assistant Sec-
8	retary for Personnel and in collaboration with the Director
9	of the Office, shall determine the extent to which women
10	are represented among senior physicians and scientists of
11	the national research institutes and among physicians and
12	scientists conducting research with funds provided by such
13	institutes, and as appropriate, carry out activities to in-
14	crease the extent of such representation.
15	"(f) Definitions.—For purposes of this part:
16	"(1) The term 'women's health conditions', with
17	respect to women of all age, ethnic, and racial groups,
18	means all diseases, disorders, and conditions (includ-
19	ing with respect to mental health)—
20	"(A) unique to, more serious, or more prev-
21	alent in women;
22	"(B) for which the factors of medical risk or
23	types of medical intervention are different for
24	women, or for which it is unknown whether such
25	factors or types are different for women; or

1	"(C) with respect to which there has been
2	insufficient clinical research involving women as
3	subjects or insufficient clinical data on women.
4	"(2) The term 'research on women's health
5	means research on women's health conditions, includ-
6	ing research on preventing such conditions.
7	"SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE
8	ON RESEARCH ON WOMEN'S HEALTH.
9	"(a) Data System.—
10	"(1) The Director of NIH, in consultation with
11	the Director of the Office and the Director of the Na-
12	tional Library of Medicine, shall establish a data sys-
13	tem for the collection, storage, analysis, retrieval, and
14	dissemination of information regarding research on
15	women's health that is conducted or supported by the
16	national research institutes. Information from the
17	data system shall be available through information
18	systems available to health care professionals and
19	providers, researchers, and members of the public.
20	"(2) The data system established under para-
21	graph (1) shall include a registry of clinical trials of
22	experimental treatments that have been developed for
23	research on women's health. Such registry shall in-
24	clude information on subject eligibility criteria, sex,

age, ethnicity or race, and the location of the trial site

25

or sites. Principal investigators of such clinical trials 1 2 shall provide this information to the registry within 30 days after it is available. Once a trial has been 3 completed, the principal investigator shall provide the registry with information pertaining to the results, 5 including potential toxicities or adverse effects associ-6 7 ated with the experimental treatment or treatments evaluated. 8 9 "(b) Clearinghouse.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health. 15 "SEC. 486B. BIENNIAL REPORT. "(a) In General.—With respect to research on wom-16 en's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report— 19 "(1) describing and evaluating the progress made 20 during the preceding 2 fiscal years in research and 21 treatment conducted or supported by the National In-22 stitutes of Health: 23 "(2) describing and analyzing the professional 24

status of women physicians and scientists of such In-

25

1	stitutes, including the identification of problems and
2	barriers regarding advancements;
3	"(3) summarizing and analyzing expenditures
4	made by the agencies of such Institutes (and by such
5	Office) during the preceding 2 fiscal years; and
6	"(4) making such recommendations for legisla-
7	tive and administrative initiatives as the Director of
8	the Office determines to be appropriate.
9	"(b) Inclusion in Biennial Report of Director
10	OF NIH.—The Director of the Office shall submit each re-
11	port prepared under subsection (a) to the Director of NIH
12	for inclusion in the report submitted to the President and
13	the Congress under section 403.".
14	(b) Requirement of Sufficient Allocation of
15	Resources of Institutes.—Section 402(b) of the Public
16	Health Service Act (42 U.S.C. 282(b)) is amended—
17	(1) in paragraph (10), by striking "and" after
18	the semicolon at the end;
19	(2) in paragraph (11), by striking the period at
20	the end and inserting "; and"; and
21	(3) by inserting after paragraph (11) the follow-
22	ing new paragraph:
23	"(12) after consultation with the Director of the
24	Office of Research on Women's Health, shall ensure
25	that resources of the National Institutes of Health are

1	sufficiently allocated for projects of research on wom-
2	en's health that are identified under section 486(b).''.
3	PART III—OFFICE OF RESEARCH ON MINORITY
4	HEALTH
5	SEC. 151. ESTABLISHMENT.
6	Part A of title IV of the Public Health Service Act
7	(42 U.S.C. 281 et seq.) is amended by adding at the end
8	the following section:
9	"OFFICE OF RESEARCH ON MINORITY HEALTH
10	"Sec. 404. (a) Establishment.—There is established
11	within the Office of the Director of NIH an office to be
12	known as the Office of Research on Minority Health (in
13	this section referred to as the 'Office'). The Office shall be
14	headed by a director, who shall be appointed by the Director
15	of NIH.
16	"(b) Purpose.—The Director of the Office shall—
17	"(1) identify projects of research on minority
18	health that should be conducted or supported by the
19	national research institutes;
20	"(2) identify multidisciplinary research relating
21	to research on minority health that should be so con-
22	ducted or supported;
23	"(3) promote coordination and collaboration
24	among entities conducting research identified under
25	paragraph (1) or (2):

1	"(4) encourage the conduct of such research by
2	entities receiving funds from the national research in-
3	stitutes;
4	"(5) recommend an agenda for conducting and
5	supporting such research;
6	"(6) promote the sufficient allocation of the re-
7	sources of the national research institutes for conduct-
8	ing and supporting such research; and
9	"(7) assist in the administration of section 492B
10	with respect to the inclusion of members of minority
11	groups as subjects in clinical research.''.
12	Subtitle C—Research Integrity
13	SEC. 161. ESTABLISHMENT OF OFFICE OF RESEARCH IN-
14	TEGRITY.
15	(a) In General.—Section 493 of the Public Health
16	Service Act (42 U.S.C. 289b) is amended to read as follows:
17	"OFFICE OF RESEARCH INTEGRITY
18	"Sec. 493. (a) Establishment.—
19	"(1) In general.—Not later than 90 days after
20	the date of enactment of this section, the Secretary
21	shall establish an office to be known as the Office of
22	Research Integrity (hereafter referred to in this sec-
23	tion as the 'Office'), which shall be established as an
24	independent entity in the Department of Health and
25	Human Services.

"(2) Director.—The Office shall be headed by 1 2 a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of 3 4 research, and have experience in the conduct of investigations of research misconduct. The Secretary shall 5 6 carry out this section acting through the Director of 7 the Office. The Director shall report to the Secretary. 8 "(b) Existence of Administrative Processes as Condition of Funding for Research.—The Secretary shall by regulation require that each entity that applies for 10 a grant, contract, or cooperative agreement under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement 14 assurances satisfactory to the Secretary that such entity— 15 16 "(1) has established (in accordance with regula-17 tions which the Secretary shall prescribe) an adminis-18 trative process to review reports of research mis-19 conduct in connection with biomedical and behavioral 20 research conducted at or sponsored by such entity; 21 and 22 "(2) will report to the Director any investigation of alleged research misconduct in connection with 23 24 projects for which funds have been made available 25 under this Act that appears substantial.

1	"(c) Process for Response of Director.—The
2	Secretary shall establish by regulation a process to be fol-
3	lowed by the Director for the prompt and appropriate—
4	"(1) response to information provided to the Di-
5	rector respecting research misconduct in connection
6	with projects for which funds have been made avail-
7	able under this Act;
8	"(2) receipt of reports by the Director of such in-
9	formation from recipients of funds under this Act;
10	"(3) conduct of investigations, when appropriate;
11	and
12	"(4) taking of other actions, including appro-
13	priate remedies, with respect to such misconduct.
14	"(d) Monitoring by Director.—The Secretary shall
15	by regulation establish procedures for the Director to mon-
16	itor administrative processes and investigations that have
17	been established or carried out under this section.
18	"(e) Effect on Present Investigations.—Nothing
19	in this section shall affect investigations which have been
20	or will be commenced prior to the promulgation of final
21	regulations under this section.".
22	(b) Establishment of Definition of Research
23	Misconduct.—Not later than 90 days after the date on
24	which the report required under section 162(d) is submitted
25	to the Secretary of Health and Human Services, such Sec-

retary shall by regulation establish a definition for the term
 "research misconduct" for purposes of section 493 of the
 Public Health Service Act, as amended by subsection (a)

5 SEC. 162. COMMISSION ON RESEARCH INTEGRITY.

- 6 (a) In General.—Not later than 90 days after the
- 7 date of the enactment of this Act, the Secretary of Health
- 8 and Human Services shall establish a commission to be
- 9 known as the Commission on Research Integrity (in this
- 10 section referred to as the "Commission").
- 11 (b) Duties.—The Commission shall develop rec-
- 12 ommendations for the Secretary of Health and Human
- 13 Services on the administration of section 493 of the Public
- 14 Health Service Act (as amended and added by section 161
- 15 of this Act).

of this section.

- 16 (c) Composition.—The Commission shall be composed
- 17 of 12 members to be appointed by the Secretary of Health
- 18 and Human Services. Not more than 3 members of the Com-
- 19 mission may be officers or employees of the United States.
- 20 Of the members of the Commission—
- 21 (1) three shall be scientists with substantial ac-22 complishments in biomedical or behavioral research;
- 23 (2) three shall be individuals with experience in 24 investigating allegations of misconduct with respect to
- 25 research research;

	10
1	(3) three shall be representatives of institutions
2	of higher education at which biomedical or behavioral
3	research is conducted; and
4	(4) three shall be individuals who are not de-
5	scribed in paragraphs (1), (2), or (3), at least one of
6	whom shall be an attorney and at least one of whom
7	shall be an ethicist.
8	(d) Compensation.—Members of the Commission
9	may not receive compensation for service on the Commis-
10	sion. Members may be reimbursed for travel, subsistence,
11	and other necessary expenses incurred in carrying out the
12	duties of the Commission.
13	(e) Report.—Not later than 120 days after the date
14	on which the Commission is established under subsection
15	(a), the Commission shall prepare and submit to the Sec-
16	retary of Health and Human Services, the Committee or
17	Energy and Commerce of the House of Representatives, and
18	the Committee on Labor and Human Resources of the Sen-
19	ate, a report containing the recommendations developed
20	under subsection (b).
21	SEC. 163. PROTECTION OF WHISTLEBLOWERS.
22	Section 493 of the Public Health Service Act, as
23	amended by section 161 of this Act, is amended by adding
24	at the end the following new subsection:

"(f) Protection of Whistleblowers.—

25

1	"(1) In general.—In the case of any entity re-
2	quired to establish administrative processes under
3	subsection (b), the Secretary shall by regulation estab-
4	lish standards for preventing, and for responding to
5	the occurrence of retaliation by such entity, its offi-
6	cials or agents, against an employee in the terms and
7	conditions of employment in response to the employee
8	having in good faith—
9	"(A) made an allegation that the entity, its
10	officials or agents, has engaged in or failed to
11	adequately respond to an allegation of research
12	misconduct; or
13	"(B) cooperated with an investigation of
14	such an allegation.
15	"(2) Monitoring by secretary.—The Sec-
16	retary shall establish by regulation procedures for the
17	Director to monitor the implementation of the stand-
18	ards established by an entity under paragraph (1) for
19	the purpose of determining whether the procedures
20	have been established, and are being utilized, in ac-
21	cordance with the standards established under such
22	paragraph.
23	"(3) Noncompliance.—The Secretary shall by
24	regulation establish remedies for noncompliance by an
25	entity, its officials or agents, which has engaged in re-

1	taliation in violation of the standards established
2	under paragraph (1). Such remedies may include ter-
3	mination of funding provided by the Secretary for
4	such project or recovery of funding being provided by
5	the Secretary for such project, or other actions as ap-
6	propriate.
7	"(4) Final rule for regulations.—The Sec-
8	retary shall issue a final rule for the regulations re-
9	quired in paragraph (1) not later than 180 days after
10	the date of the enactment of the National Institutes of
11	Health Revitalization Act of 1993.
12	"(5) Required agreements.—For any fiscal
13	year beginning after the date on which the regulations
14	required in paragraph (1) are issued, the Secretary
15	may not provide a grant, cooperative agreement, or
16	contract under this Act for biomedical or behavioral
17	research unless the entity seeking such financial as-
18	sistance agrees that the entity—
19	"(A) will maintain the procedures described
20	in the regulations; and
21	"(B) will otherwise be subject to the regula-
22	tions.".

1	SEC. 164. REQUIREMENT OF REGULATIONS REGARDING
2	PROTECTION AGAINST FINANCIAL CON-
3	FLICTS OF INTEREST IN CERTAIN PROJECTS
4	OF RESEARCH.
5	Part H of title IV of the Public Health Service Act,
6	as redesignated by section 141(a)(2) of this Act, is amended
7	by inserting after section 493 the following new section:
8	"PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST
9	IN CERTAIN PROJECTS OF RESEARCH
10	"Sec. 493A. (a) Issuance of Regulations.—
11	"(1) In general.—The Secretary shall define by
12	regulation, the specific circumstances that constitute
13	the existence of a financial interest in a project on the
14	part of an entity or individual that will, or may be
15	reasonably expected to, create a bias in favor of ob-
16	taining results in such project that are consistent
17	with such financial interest. Such definition shall
18	apply uniformly to each entity or individual conduct-
19	ing a research project under this Act. In the case of
20	any entity or individual receiving assistance from the
21	Secretary for a project of research described in para-
22	graph (2), the Secretary shall by regulation establish
23	standards for responding to, including managing, re-
24	ducing, or eliminating, the existence of such a finan-
25	cial interest. The entity may adopt individualized
26	procedures for implementing the standards.

"(2) Relevant projects.—A project of research referred to in paragraph (1) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

"(3) Identifying and reporting to the director.—The Secretary shall ensure that the standards established under paragraph (1) specify that as a condition of receiving assistance from the Secretary for the project involved, an entity described in such subsection is required—

"(A) to have in effect at the time the entity applies for the assistance and throughout the period during which the assistance is received, a process for identifying such financial interests as defined in paragraph (1) that exist regarding the project; and

"(B) to report to the Director such financial interest as defined in paragraph (1) identified by the entity and how any such financial interest identified by the entity will be managed or eliminated such that the project in question will be protected from bias that may stem from such financial interest.

1	"(4) Monitoring of process.—The Secretary
2	shall monitor the establishment and conduct of the
3	process established by an entity pursuant to para-
4	graph (1).
5	"(5) Response.—In any case in which the Sec-
6	retary determines that an entity has failed to comply
7	with paragraph (3) regarding a project of research
8	described in paragraph (1), the Secretary—
9	"(A) shall require that, as a condition of re-
10	ceiving assistance, the entity disclose the exist-
11	ence of a financial interest as defined in para-
12	graph (1) in each public presentation of the re-
13	sults of such project; and
14	"(B) may take such other actions as the
15	Secretary determines to be appropriate.
16	"(6) Definition.—As used in this section:
17	"(A) The term 'financial interest' includes
18	the receipt of consulting fees or honoraria and
19	the ownership of stock or equity.
20	"(B) The term 'assistance', with respect to
21	conducting a project of research, means a grant,
22	contract, or cooperative agreement.
23	"(b) Final Rule for Regulations.—The Secretary
24	shall issue a final rule for the regulations required in sub-
2.5	section (a) not later than 180 days after the date of the

- 1 enactment of the National Institutes of Health Revitaliza-
- 2 tion Act of 1993.".

3 SEC. 165. EFFECTIVE DATES.

- 4 (a) In General.—The amendments made by this sub-
- 5 title shall become effective on the date that occurs 180 days
- 6 after the date on which the final rule required under section
- 7 493(f)(4) of the Public Health Service Act, as amended by
- 8 sections 161 and 163, is published in the Federal Register.
- 9 (b) AGREEMENTS AS A CONDITION OF FUNDING.—The
- 10 requirements of subsection (f) (5) of section 493 of the Public
- 11 Health Service Act, as amended by sections 161 and 163,
- 12 with respect to agreements as a condition of funding shall
- 13 not be effective in the case of projects of research for which
- 14 initial funding under the Public Health Service Act was
- 15 provided prior to the effective date described in subsection
- 16 (a).

17 TITLE II—NATIONAL INSTITUTES

18 **OF HEALTH IN GENERAL**

- 19 SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINATION.
- 20 Section 402(f) of the Public Health Service Act (42
- 21 U.S.C. 282(f)) is amended by striking "other public and
- 22 private entities." and all that follows through the end and
- 23 inserting "other public and private entities, including ele-
- 24 mentary, secondary, and post-secondary schools. The Asso-
- 25 ciate Director shall—

1	"(1) annually review the efficacy of existing poli-
2	cies and techniques used by the national research in-
3	stitutes to disseminate the results of disease preven-
4	tion and behavioral research programs;
5	"(2) recommend, coordinate, and oversee the
6	modification or reconstruction of such policies and
7	techniques to ensure maximum dissemination, using
8	advanced technologies to the maximum extent prac-
9	ticable, of research results to such entities; and
10	"(3) annually prepare and submit to the Direc-
11	tor of NIH a report concerning the prevention and
12	dissemination activities undertaken by the Associate
13	Director, including—
14	"(A) a summary of the Associate Director's
15	review of existing dissemination policies and
16	techniques together with a detailed statement
17	concerning any modification or restructuring, or
18	recommendations for modification or restructur-
19	ing, of such policies and techniques; and
20	"(B) a detailed statement of the expendi-
21	tures made for the prevention and dissemination
22	activities reported on and the personnel used in
23	connection with such activities.".

1	SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARD-
2	ING CERTAIN STATES AND RESEARCHERS.
3	Section 402 of the Public Health Service Act (42
4	U.S.C. 282) is amended by adding at the end the following
5	new subsection:
6	" $(g)(1)(A)$ In the case of entities described in subpara-
7	graph (B), the Director of NIH, acting through the Director
8	of the National Center for Research Resources, shall estab-
9	lish a program to enhance the competitiveness of such enti-
10	ties in obtaining funds from the national research institutes
11	for conducting biomedical and behavioral research.
12	"(B) The entities referred to in subparagraph (A) are
13	entities that conduct biomedical and behavioral research
14	and are located in a State in which the aggregate success
15	rate for applications to the national research institutes for
16	assistance for such research by the entities in the State has
17	historically constituted a low success rate of obtaining such
18	funds, relative to such aggregate rate for such entities in
19	other States.
20	"(C) With respect to enhancing competitiveness for
21	purposes of subparagraph (A), the Director of NIH, in car-
22	rying out the program established under such subpara-
23	graph, may—
24	"(i) provide technical assistance to the entities
25	involved, including technical assistance in the prepa-

1	ration of applications for obtaining funds from the
2	national research institutes;
3	"(ii) assist the entities in developing a plan for
4	biomedical or behavioral research proposals; and
5	"(iii) assist the entities in implementing such
6	plan.
7	"(2) The Director of NIH shall establish a program
8	of supporting projects of biomedical or behavioral research
9	whose principal researchers are individuals who have not
10	previously served as the principal researchers of such
11	projects supported by the Director.".
12	SEC. 203. ESTABLISHMENT OF OFFICE OF BEHAVIORAL RE-
13	SEARCH.
13 14	SEARCH. Part A of title IV of the Public Health Service Act,
14	Part A of title IV of the Public Health Service Act,
14 15	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by add-
14 15 16 17	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section:
14 15 16 17 18	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH
14 15 16 17 18	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH" "SEC. 404A. (a) There is established within the Office
14 15 16 17 18 19 20	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH" "SEC. 404A. (a) There is established within the Office of the Director of NIH an office to be known as the Office
14 15 16 17 18 19 20	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH" "Sec. 404A. (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral Research (in this section referred to as the
14 15 16 17 18 19 20 21	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH" "SEC. 404A. (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral Research (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall
14 15 16 17 18 19 20 21 22 23	Part A of title IV of the Public Health Service Act, as amended by section 151 of this Act, is amended by adding at the end the following new section: "OFFICE OF BEHAVIORAL RESEARCH "SEC. 404A. (a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral Research (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

- 1 shall coordinate research conducted or supported by the
- 2 agencies of the National Institutes of Health.
- 3 "(2) Research authorized under paragraph (1) in-
- 4 cludes research on teen pregnancy, infant mortality, violent
- 5 behavior, suicide, and homelessness.
- 6 "(3) The sole responsibility of the Director of the Office
- 7 shall be carrying out paragraph (1).''.

8 SEC. 204. CHILDREN'S VACCINE INITIATIVE.

- 9 Part A of title IV of the Public Health Service Act,
- 10 as amended by section 203 of this Act, is amended by add-
- 11 ing at the end the following new section:
- 12 "CHILDREN'S VACCINE INITIATIVE
- 13 "Sec. 404B. (a) Development of New Vaccines.—
- 14 The Secretary, in consultation with the Director of the Na-
- 15 tional Vaccine Program under title XXI and acting through
- 16 the Directors of the National Institute for Allergy and Infec-
- 17 tious Diseases, the National Institute for Child Health and
- 18 Human Development, the National Institute for Aging, and
- 19 other public and private programs, shall carry out activi-
- 20 ties, which shall be consistent with the global Children's
- 21 Vaccine Initiative, to develop affordable new and improved
- 22 vaccines to be used in the United States and in the develop-
- 23 ing world that will increase the efficacy and efficiency of
- 24 the prevention of infectious diseases. In carrying out such
- 25 activities, the Secretary shall, to the extent practicable, de-
- 26 velop and make available vaccines that require fewer con-

- 1 tacts to deliver, that can be given early in life, that provide
- 2 long lasting protection, that obviate refrigeration, needles
- 3 and syringes, and that protect against a larger number of
- 4 diseases.
- 5 "(b) Report.—In the report required in section 2104,
- 6 the Secretary, acting through the Director of the National
- 7 Vaccine Program under title XXI, shall include information
- 8 with respect to activities and the progress made in imple-
- 9 menting the provisions of this section and achieving its
- 10 goals.
- 11 "(c) Authorization of Appropriations.—In addi-
- 12 tion to any other amounts authorized to be appropriated
- 13 for activities of the type described in this section, there are
- 14 authorized to be appropriated to carry out this section
- 15 *\$50,000,000 for fiscal year 1994, and such sums as may*
- 16 be necessary for each of the fiscal years 1995 and 1996.".
- 17 SEC. 205. PLAN FOR USE OF ANIMALS IN RESEARCH.
- 18 (a) IN GENERAL.—Part A of title IV of the Public
- 19 Health Service Act, as amended by section 204 of this Act,
- 20 is amended by adding at the end the following new section:
- 21 "PLAN FOR USE OF ANIMALS IN RESEARCH
- 22 "Sec. 404C. (a) The Director of NIH, after consulta-
- 23 tion with the committee established under subsection (e),
- 24 shall prepare a plan—
- 25 "(1) for the National Institutes of Health to con-
- 26 duct or support research into—

1	"(A) methods of biomedical research and ex-
2	perimentation that do not require the use of ani-
3	mals;
4	"(B) methods of such research and experi-
5	mentation that reduce the number of animals
6	used in such research;
7	"(C) methods of such research and experi-
8	mentation that produce less pain and distress in
9	such animals; and
10	"(D) methods of such research and experi-
11	mentation that involve the use of marine life
12	(other than marine mammals);
13	"(2) for establishing the validity and reliability
14	of the methods described in paragraph (1);
15	"(3) for encouraging the acceptance by the sci-
16	entific community of such methods that have been
17	found to be valid and reliable; and
18	"(4) for training scientists in the use of such
19	methods that have been found to be valid and reliable.
20	"(b) Not later than October 1, 1993, the Director of
21	NIH shall submit to the Committee on Energy and Com-
22	merce of the House of Representatives, and to the Committee
23	on Labor and Human Resources of the Senate, the plan
24	required in subsection (a) and shall begin implementation
25	of the plan.

- 1 "(c) The Director of NIH shall periodically review,
- 2 and as appropriate, make revisions in the plan required
- 3 under subsection (a). A description of any revision made
- 4 in the plan shall be included in the first biennial report
- 5 under section 403 that is submitted after the revision is
- 6 made.
- 7 "(d) The Director of NIH shall take such actions as
- 8 may be appropriate to convey to scientists and others who
- 9 use animals in biomedical or behavioral research or experi-
- 10 mentation information respecting the methods found to be
- 11 valid and reliable under subsection (a) (2).
- 12 "(e)(1) The Director of NIH shall establish within the
- 13 National Institutes of Health a committee to be known as
- 14 the Interagency Coordinating Committee on the Use of Ani-
- 15 mals in Research (hereafter in this subsection referred to
- 16 as the 'Committee').
- 17 "(2) The Committee shall provide advice to the Direc-
- 18 tor of NIH on the preparation of the plan required in sub-
- 19 section (a).
- 20 "(3) The Committee shall be composed of—
- 21 "(A) the Directors of each of the national re-
- search institutes and the Director of the Center for
- 23 Research Resources (or the designees of such Direc-
- 24 tors); and

1	"(B) representatives of the Environmental Pro-
2	tection Agency, the Food and Drug Administration,
3	the Consumer Product Safety Commission, the Na-
4	tional Science Foundation, and such additional agen-
5	cies as the Director of NIH determines to be appro-
6	priate.''.
7	(b) Conforming Amendment.—Section 4 of the
8	Health Research Extension Act of 1985 (Public Law 99-
9	158; 99 Stat. 880) is repealed.
10	SEC. 206. INCREASED PARTICIPATION OF WOMEN AND DIS-
11	ADVANTAGED INDIVIDUALS IN FIELDS OF
12	BIOMEDICAL AND BEHAVIORAL RESEARCH.
12	BIOMEDICAL AND BEHAVIORAL RESEARCH.
12 13	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as
12 13 14	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding
12 13 14 15	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection:
12 13 14 15 16 17	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection: "(h) The Secretary, acting through the Director of NIH
12 13 14 15 16 17	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection: "(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes
12 13 14 15 16 17	BIOMEDICAL AND BEHAVIORAL RESEARCH. Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection: "(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, may conduct and support programs for research,
12 13 14 15 16 17 18 19	Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection: "(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, may conduct and support programs for research, research training, recruitment, and other activities to pro-

1	SEC. 207. REQUIREMENTS REGARDING SURVEYS OF SEXUAL
2	BEHAVIOR.
3	Part A of title IV of the Public Health Service Act
4	as amended by section 205 of this Act, is amended by add
5	ing at the end the following new section:
6	"REQUIREMENTS REGARDING SURVEYS OF SEXUAL
7	<i>BEHAVIOR</i>
8	"Sec. 404D. With respect to any survey of human sex
9	ual behavior proposed to be conducted or supported through
10	the National Institutes of Health, the survey may not be
11	carried out unless—
12	"(1) the proposal has undergone review in ac-
13	cordance with any applicable requirements of sections
14	491 and 492; and
15	"(2) the Secretary, in accordance with section
16	492A, makes a determination that the information ex-
17	pected to be obtained through the survey will assist—
18	"(A) in reducing the incidence of sexually
19	transmitted diseases, the incidence of infection
20	with the human immunodeficiency virus, or the
21	incidence of any other infectious disease; or
22	"(B) in improving reproductive health or
23	other conditions of health.".

1	SEC. 208. DISCRETIONARY FUND OF DIRECTOR OF NA-
2	TIONAL INSTITUTES OF HEALTH.
3	Section 402 of the Public Health Service Act, as
4	amended by section 206 of this Act, is amended by adding
5	at the end the following new subsection:
6	``(i)(1) There is established a fund, consisting of
7	amounts appropriated under paragraph (3) and made
8	available for the fund, for use by the Director of NIH to
9	carry out the activities authorized in this Act for the Na-
10	tional Institutes of Health. The purposes for which such
11	fund may be expended include—
12	"(A) providing for research on matters that have
13	not received significant funding relative to other mat-
14	ters, responding to new issues and scientific emer-
15	gencies, and acting on research opportunities of high
16	priority;
17	"(B) supporting research that is not exclusively
18	within the authority of any single agency of such In-
19	stitutes; and
20	"(C) purchasing or renting equipment and quar-
21	ters for activities of such Institutes.
22	"(2) Not later than February 10 of each fiscal year,
23	the Secretary shall submit to the Committee on Energy and
24	Commerce of the House of Representatives, and to the Com-
25	mittee on Labor and Human Resources of the Senate, a
26	report describing the activities undertaken and expenditures

- 1 made under this section during the preceding fiscal year.
- 2 The report may contain such comments of the Secretary re-
- 3 garding this section as the Secretary determines to be ap-
- 4 propriate.
- 5 "(3) For the purpose of carrying out this subsection,
- 6 there are authorized to be appropriated \$25,000,000 for fis-
- 7 cal year 1994, and such sums as may be necessary for each
- 8 of the fiscal years 1995 and 1996.".
- 9 SEC. 209. ESTABLISHMENT OF OFFICE OF ALTERNATIVE
- 10 **MEDICINE**.
- 11 Part A of title IV of the Public Health Service Act,
- 12 as amended by section 207 of this Act, is amended by add-
- 13 ing at the end the following section:
- 14 "OFFICE OF ALTERNATIVE MEDICINE
- 15 "Sec. 404E. (a) There is established within the Office
- 16 of the Director of NIH an office to be known as the Office
- 17 of Alternative Medicine (in this section referred to as the
- 18 'Office'), which shall be headed by a director appointed by
- 19 the Director of NIH.
- 20 "(b) The purpose of the Office is to facilitate the eval-
- 21 uation of various alternative medicine treatment modali-
- 22 ties, including acupuncture and Oriental medicine, homeo-
- 23 pathic medicine, and physical manipulation therapies.
- 24 "(c) In carrying out subsection (b), the Director of the
- 25 Office shall—

1	"(1) establish an information clearinghouse to
2	exchange information with the public about alter-
3	native medicine;
4	"(2) support research training—
5	"(A) for which fellowship support is not
6	provided under section 487; and
7	"(B) that is not residency training of physi-
8	cians or other health professionals; and
9	"(3) submit an annual report on past and future
10	activities of the Office, each of which reports shall be
11	submitted to the Committee on Energy and Commerce
12	of the House of Representatives and the Committee on
13	Labor and Human Resources of the Senate.".
14	SEC. 210. MISCELLANEOUS PROVISIONS.
15	(a) Term of Office for Members of Advisory
16	Councils.—Section 406(c) of the Public Health Service
17	Act (42 U.S.C. 284a(c)) is amended in the second sentence
18	by striking "until a successor has taken office" and insert-
19	ing the following: "for 180 days after the date of such expi-
20	ration".
21	(b) Literacy Requirements.—Section 402(e) of the
22	Public Health Service Act (42 U.S.C. 282(e)) is amended—
23	(1) in paragraph (3), by striking "and" at the
24	end;

- 1 (2) in paragraph (4), by striking the period and 2 inserting "; and"; and
- 3 (3) by adding at the end thereof the following4 new paragraph:
- 5 "(5) ensure that, after January 1, 1994, at least 6 one-half of all new or revised health education and 7 promotion materials developed or funded by the Na-8 tional Institutes of Health is in a form that does not 9 exceed a level of functional literacy, as defined in the 10 National Literacy Act of 1991 (Public Law 102– 11 73)."
- 12 (c) Day Care Regarding Children of Employ-
- 13 EES.—Section 402 of the Public Health Service Act, as
- 14 amended by section 208 of this Act, is amended by adding
- 15 at the end the following new subsection:
- 16 "(j)(1) The Director of NIH may establish a program
- 17 to provide day care services for the employees of the Na-
- 18 tional Institutes of Health similar to those services provided
- 19 by other Federal agencies (including the availability of day
- 20 care service on a 24-hour-a-day basis).
- 21 "(2) Any day care provider at the National Institutes
- 22 of Health shall establish a sliding scale of fees that takes
- 23 into consideration the income and needs of the employee.

1	"(3) For purposes regarding the provision of day care
2	services, the Director of NIH may enter into rental or lease
3	purchase agreements.''.
4	TITLE III—GENERAL PROVI-
5	SIONS RESPECTING NA-
6	TIONAL RESEARCH INSTI-
7	TUTES
8	SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS
9	OF NATIONAL RESEARCH INSTITUTES.
10	(a) Establishment of General Authority Re-
11	Garding Direct Funding.—
12	(1) In general.—Section 405(b)(2) of the Pub-
13	lic Health Service Act (42 U.S.C. 284(b)(2)) is
14	amended—
15	(A) in subparagraph (A), by striking "and"
16	after the semicolon at the end;
17	(B) in subparagraph (B), by striking the
18	period at the end and inserting "; and"; and
19	(C) by adding at the end the following new
20	subparagraph:
21	"(C) shall receive from the President and the Of-
22	fice of Management and Budget directly all funds ap-
23	propriated by the Congress for obligation and expend-
24	iture by the Institute.''.

1	(2) Conforming amendment.—Section
2	413(b)(9) of the Public Health Service Act (42 U.S.C.
3	285a-2(b)(9)) is amended—
4	(A) by striking "(A)" after "(9)"; and
5	(B) by striking "advisory council;" and all
6	that follows and inserting "advisory council.".
7	(b) Appointment and Duration of Technical and
8	Scientific Peer Review Groups.—Section 405(c) of the
9	Public Health Service Act (42 U.S.C. 284(c)) is amended—
10	(1) by amending paragraph (3) to read as fol-
11	lows:
12	"(3) may, in consultation with the advisory
13	council for the Institute and with the approval of the
14	Director of NIH—
15	"(A) establish technical and scientific peer
16	review groups in addition to those appointed
17	under section 402(b)(6); and
18	"(B) appoint the members of peer review
19	groups established under subparagraph (A);
20	and"; and
21	(2) by adding after and below paragraph (4) the
22	following:
23	"The Federal Advisory Committee Act shall not apply to
24	the duration of a peer review group appointed under para-
25	graph (3). ''.

1	SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS,
2	PAGET'S DISEASE, AND RELATED BONE DIS-
3	ORDERS.
4	Part B of title IV of the Public Health Service Act
5	(42 U.S.C. 284 et seq.), as amended by section 121(b) of
6	Public Law 102-321 (106 Stat. 358), is amended by adding
7	at the end the following new section:
8	"RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND
9	RELATED BONE DISORDERS
10	"Sec. 409A. (a) Establishment.—The Directors of
11	the National Institute of Arthritis and Musculoskeletal and
12	Skin Diseases, the National Institute on Aging, and the Na-
13	tional Institute of Diabetes, Digestive and Kidney Diseases,
14	shall expand and intensify the programs of such Institutes
15	with respect to research and related activities concerning
16	osteoporosis, Paget's disease, and related bone disorders.
17	"(b) Coordination.—The Directors referred to in sub-
18	section (a) shall jointly coordinate the programs referred
19	to in such subsection and consult with the Arthritis and
20	Musculoskeletal Diseases Interagency Coordinating Com-
21	mittee and the Interagency Task Force on Aging Research.
22	"(c) Information Clearinghouse.—
23	"(1) In general.—In order to assist in carry-
24	ing out the purpose described in subsection (a), the
25	Director of NIH shall provide for the establishment of
26	an information clearinghouse on osteoporosis and re-

- lated bone disorders to facilitate and enhance knowl edge and understanding on the part of health profes sionals, patients, and the public through the effective
- 4 dissemination of information.
- 5 "(2) ESTABLISHMENT THROUGH GRANT OR CON-6 TRACT.—For the purpose of carrying out paragraph 7 (1), the Director of NIH shall enter into a grant, co-8 operative agreement, or contract with a nonprofit pri-9 vate entity involved in activities regarding the pre-10 vention and control of osteoporosis and related bone 11 disorders.
- "(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years
- 16 1995 and 1996.".
- 17 SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM
- 18 FOR TRAUMA RESEARCH.
- 19 (a) In General.—Title XII of the Public Health Serv-
- 20 ice Act (42 U.S.C. 300d et seq.), as amended by title VI
- 21 of Public Law 102–321 (106 Stat. 433) and section 304
- 22 of Public Law 102–408 (106 Stat. 2084), is amended by
- 23 adding at the end the following part:

1	"Part F—Interagency Program for Trauma
2	Research
3	"SEC. 1261. ESTABLISHMENT OF PROGRAM.
4	"(a) In General.—The Secretary, acting through the
5	Director of the National Institutes of Health (hereafter in
6	this section referred to as the 'Director'), shall establish a
7	comprehensive program of conducting basic and clinical re-
8	search on trauma (hereafter in this section referred to as
9	the 'Program'). The Program shall include research regard-
10	ing the diagnosis, treatment, rehabilitation, and general
11	management of trauma.
12	"(b) Plan for Program.—
13	"(1) In general.—The Director, in consultation
14	with the Trauma Research Interagency Coordinating
15	Committee established under subsection (g), shall es-
16	tablish and implement a plan for carrying out the ac-
17	tivities of the Program, including the activities de-
18	scribed in subsection (d). All such activities shall be
19	carried out in accordance with the plan. The plan
20	shall be periodically reviewed, and revised as appro-
21	priate.
22	"(2) Submission to congress.—Not later than
23	June 1, 1993, the Director shall submit the plan re-
24	quired in paragraph (1) to the Committee on Energy
25	and Commerce of the House of Representatives, and

1	to the Committee on Labor and Human Resources of
2	the Senate, together with an estimate of the funds
3	needed for each of the fiscal years 1994 through 1996
4	to implement the plan.
5	"(c) Participating Agencies; Coordination and
6	Collaboration.—The Director—
7	"(1) shall provide for the conduct of activities
8	under the Program by the Directors of the agencies of
9	the National Institutes of Health involved in research
10	with respect to trauma;
11	"(2) shall ensure that the activities of the Pro-
12	gram are coordinated among such agencies; and
13	"(3) shall, as appropriate, provide for collabora-
14	tion among such agencies in carrying out such activi-
15	ties.
16	"(d) CERTAIN ACTIVITIES OF PROGRAM.—The Pro-
17	gram shall include—
18	"(1) studies with respect to all phases of trauma
19	care, including prehospital, resuscitation, surgical
20	intervention, critical care, infection control, wound
21	healing, nutritional care and support, and medical
22	rehabilitation care;
23	"(2) basic and clinical research regarding the re-
24	sponse of the body to trauma and the acute treatment

1	and medical rehabilitation of individuals who are the
2	victims of trauma; and
3	"(3) basic and clinical research regarding trau-
4	ma care for pediatric and geriatric patients.
5	"(e) Mechanisms of Support.—In carrying out the
6	Program, the Director, acting through the Directors of the
7	agencies referred to in subsection (c)(1), may make grants
8	to public and nonprofit entities, including designated trau-
9	ma centers.
10	"(f) Resources.—The Director shall assure the avail-
11	ability of appropriate resources to carry out the Program,
12	including the plan established under subsection (b) (includ-
13	ing the activities described in subsection (d)).
14	"(g) Coordinating Committee.—
15	"(1) In GENERAL.—There shall be established a
16	Trauma Research Interagency Coordinating Commit-
17	tee (hereafter in this section referred to as the 'Coordi-
18	nating Committee').
19	"(2) Duties.—The Coordinating Committee
20	shall make recommendations regarding—
21	"(A) the activities of the Program to be car-
22	ried out by each of the agencies represented on
23	the Committee and the amount of funds needed
24	by each of the agencies for such activities; and

1	"(B) effective collaboration among the agen-
2	cies in carrying out the activities.
3	"(3) Composition.—The Coordinating Commit-
4	tee shall be composed of the Directors of each of the
5	agencies that, under subsection (c), have responsibil-
6	ities under the Program, and any other individuals
7	who are practitioners in the trauma field as des-
8	ignated by the Director of the National Institutes of
9	Health.
10	"(h) Definitions.—For purposes of this section:
11	"(1) The term 'designated trauma center' has the
12	meaning given such term in section 1231(1).
13	"(2) The term 'Director' means the Director of
14	the National Institutes of Health.
15	"(3) The term 'trauma' means any serious in-
16	jury that could result in loss of life or in significant
17	disability and that would meet pre-hospital triage
18	criteria for transport to a designated trauma center.".
19	(b) Conforming Amendment.—Section 402 of the
20	Public Health Service Act, as amended by section 210(c)
21	of this Act, is amended by adding at the end the following
22	new subsection:
23	"(k) The Director of NIH shall carry out the program
24	established in part E of title XII (relating to interagency
25	research on trauma).".

TITLE IV—NATIONAL CANCER 1 INSTITUTE 2 SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVI-4 TIES REGARDING BREAST CANCER. 5 Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following new section: 7 "BREAST AND GYNECOLOGICAL CANCERS 8 "Sec. 417. (a) Expansion and Coordination of Ac-9 TIVITIES.—The Director of the Institute, in consultation 10 with the National Cancer Advisory Board, shall expand, 11 intensify, and coordinate the activities of the Institute with 12 respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women. "(b) Coordination With Other Institutes.—The 15 Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities 17 conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive sys-21 tem of women. 23 "(c) Programs for Breast Cancer.— 24 "(1) In GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or sup-25

1	port research to expand the understanding of the
2	cause of, and to find a cure for, breast cancer. Activi-
3	ties under such subsection shall provide for an expan-
4	sion and intensification of the conduct and support
5	of—
6	"(A) basic research concerning the etiology
7	and causes of breast cancer;
8	"(B) clinical research and related activities
9	concerning the causes, prevention, detection and
10	treatment of breast cancer;
11	"(C) control programs with respect to breast
12	cancer in accordance with section 412, including
13	community-based programs designed to assist
14	women who are members of medically under-
15	served populations, low-income populations, or
16	minority groups;
17	"(D) information and education programs
18	with respect to breast cancer in accordance with
19	section 413; and
20	"(E) research and demonstration centers
21	with respect to breast cancer in accordance with
22	section 414, including the development and oper-
23	ation of centers for breast cancer research to
24	bring together basic and clinical, biomedical and
25	behavioral scientists to conduct basic, clinical,

epidemiological, psychosocial, prevention and
 treatment research and related activities on
 breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

"(2) Implementation of plan for pro-Grams.—

"(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

1	"(B) Not later than May 1, 1993, the Direc-
2	tor of the Institute shall submit a copy of the
3	plan to the President's Cancer Panel, the Sec-
4	retary and the Director of NIH.
5	"(C) The Director of the Institute shall sub-
6	mit any revisions of the plan to the President's
7	Cancer Panel, the Secretary, and the Director of
8	NIH.
9	"(D) The Secretary shall provide a copy of
10	the plan submitted under subparagraph (A), and
11	any revisions submitted under subparagraph
12	(C), to the Committee on Energy and Commerce
13	of the House of Representatives and the Commit-
14	tee on Labor and Human Resources of the Sen-
15	ate.
16	"(d) OTHER CANCERS.—In carrying out subsection
17	(a), the Director of the Institute shall conduct or support
18	research on ovarian cancer and other cancers of the repro-
19	ductive system of women. Activities under such subsection
20	shall provide for the conduct and support of—
21	"(1) basic research concerning the etiology and
22	causes of ovarian cancer and other cancers of the re-
23	productive system of women;
24	"(2) clinical research and related activities into
25	the causes, prevention, detection and treatment of

1	ovarian cancer and other cancers of the reproductive
2	system of women;
3	"(3) control programs with respect to ovarian
4	cancer and other cancers of the reproductive system of
5	women in accordance with section 412;
6	"(4) information and education programs with
7	respect to ovarian cancer and other cancers of the re-
8	productive system of women in accordance with sec-
9	tion 413; and
10	"(5) research and demonstration centers with re-
11	spect to ovarian cancer and cancers of the reproduc-
12	tive system in accordance with section 414.
13	"(e) Report.—The Director of the Institute shall pre-
14	pare, for inclusion in the biennial report submitted under
15	section 407, a report that describes the activities of the Na-
16	tional Cancer Institute under the research programs re-
17	ferred to in subsection (a), that shall include—
18	"(1) a description of the research plan with re-
19	spect to breast cancer prepared under subsection (c);
20	"(2) an assessment of the development, revision,
21	and implementation of such plan;
22	"(3) a description and evaluation of the progress
23	made, during the period for which such report is pre-
24	pared, in the research programs on breast cancer and
25	cancers of the reproductive system of women:

1	"(4) a summary and analysis of expenditures
2	made, during the period for which such report is
3	made, for activities with respect to breast cancer and
4	cancers of the reproductive system of women con-
5	ducted and supported by the National Institutes of
6	Health; and
7	"(5) such comments and recommendations as the
8	Director considers appropriate.''.
9	SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVI-
10	TIES REGARDING PROSTATE CANCER.
11	Subpart 1 of part C of title IV of the Public Health
12	Service Act, as amended by section 401 of this Act, is
13	amended by adding at the end the following new section:
14	"PROSTATE CANCER
15	"Sec. 417A. (a) Expansion and Coordination of
16	Activities.—The Director of the Institute, in consultation
17	with the National Cancer Advisory Board, shall expand,
18	intensify, and coordinate the activities of the Institute with
19	respect to research on prostate cancer.
20	"(b) Coordination With Other Institutes.—The
21	Director of the Institute shall coordinate the activities of
22	the Director under subsection (a) with similar activities
23	conducted by other national research institutes and agencies
24	of the National Institutes of Health to the extent that such
25	Institutes and agencies have responsibilities that are related
26	to prostate cancer.

1	"(c) Programs.—
2	"(1) In GENERAL.—In carrying out subsection
3	(a), the Director of the Institute shall conduct or sup-
4	port research to expand the understanding of the
5	cause of, and to find a cure for, prostate cancer. Ac-
6	tivities under such subsection shall provide for an ex-
7	pansion and intensification of the conduct and sup-
8	port of—
9	"(A) basic research concerning the etiology
10	and causes of prostate cancer;
11	"(B) clinical research and related activities
12	concerning the causes, prevention, detection and
13	treatment of prostate cancer;
14	"(C) prevention and control and early de-
15	tection programs with respect to prostate cancer
16	in accordance with section 412, particularly as
17	it relates to intensifying research on the role of
18	prostate specific antigen for the screening and
19	early detection of prostate cancer;
20	"(D) an Inter-Institute Task Force, under
21	the direction of the Director of the Institute, to
22	provide coordination between relevant National
23	Institutes of Health components of research ef-
24	forts on prostate cancer;

1	"(E) control programs with respect to pros-
2	tate cancer in accordance with section 412;
3	"(F) information and education programs
4	with respect to prostate cancer in accordance
5	with section 413; and
6	"(G) research and demonstration centers
7	with respect to prostate cancer in accordance
8	with section 414, including the development and
9	operation of centers for prostate cancer research
10	to bring together basic and clinical, biomedical
11	and behavioral scientists to conduct basic, clini-
12	cal, epidemiological, psychosocial, prevention
13	and control, treatment, research, and related ac-
14	tivities on prostate cancer.
15	Not less than six centers shall be operated under sub-
16	paragraph (G). Activities of such centers should in-
17	clude supporting new and innovative research and
18	training programs for new researchers. Such centers
19	shall give priority to expediting the transfer of re-
20	search advances to clinical applications.
21	"(2) Implementation of plan for pro-
22	GRAMS.—
23	"(A) The Director of the Institute shall en-
24	sure that the research programs described in
25	paragraph (1) are implemented in accordance

with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

- "(B) Not later than May 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.
- "(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.
- "(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.".

1 SEC. 403. AUTHORIZATION OF APPROPRIATIONS.

2	(a) In General.—Subpart 1 of part C of title IV of
3	the Public Health Service Act, as amended by section 402
4	of this Act, is amended by adding at the end the following
5	new section:
6	"AUTHORIZATION OF APPROPRIATIONS
7	"Sec. 417B. (a) Activities Generally.—For the
8	purpose of carrying out this subpart, there are authorized
9	to be appropriated \$3,200,000,000 for fiscal year 1994, and
10	such sums as may be necessary for each of the fiscal years
11	1995 and 1996.
12	"(b) Breast Cancer and Gynecological Can-
13	CERS.—
14	"(1) Breast cancer.—
15	"(A) For the purpose of carrying out sub-
16	paragraph (A) of section 417(c)(1), there are au-
17	thorized to be appropriated \$225,000,000 for fis-
18	cal year 1994, and such sums as may be nec-
19	essary for each of the fiscal years 1995 and 1996.
20	Such authorizations of appropriations are in ad-
21	dition to the authorizations of appropriations es-
22	tablished in subsection (a) with respect to such
23	purpose.
24	"(B) For the purpose of carrying out sub-
25	paragraphs (B) through (E) of section 417(c)(1),
26	there are authorized to be appropriated

\$100,000,000 for fiscal year 1994, and such sums 1 2 as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appro-3 priations are in addition to the authorizations of 4 appropriations established in subsection (a) with 5 6 respect to such purpose. 7 "(2) Other cancers.—For the purpose of car-8 rying out subsection (d) of section 417, there are authorized to be appropriated \$75,000,000 for fiscal 9 10 year 1994, and such sums as are necessary for each of the fiscal years 1995 and 1996. Such authoriza-11 12 tions of appropriations are in addition to the authorizations of appropriations established in subsection 13 14 (a) with respect to such purpose. 15 "(c) Prostate Cancer.—For the purpose of carrying out section 417A, there are authorized to be appropriated 16 17 \$72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose. 21 22 "(d) Allocation Regarding Cancer Control.— "(1) In GENERAL.—Of the amounts appro-23 24 priated for the National Cancer Institute for a fiscal 25

year, the Director of the Institute shall make available

1	not less than the applicable percentage specified in
2	paragraph (2) for carrying out the cancer control ac-
3	tivities authorized in section 412 and for which budg-
4	et estimates are made under section 413(b)(9) for the
5	fiscal year.
6	"(2) Applicable percentage.—The percentage
7	referred to in paragraph (1) is—
8	"(A) 7 percent, in the case of fiscal year
9	1994;
10	"(B) 9 percent, in the case of fiscal year
11	1995; and
12	"(C) 10 percent, in the case of fiscal year
13	1996 and each subsequent fiscal year.".
14	(b) Conforming Amendments.—
15	(1) In general.—Section 408 of the Public
16	Health Service Act (42 U.S.C. 284c) is amended—
17	(A) by striking subsection (a);
18	(B) by redesignating subsection (b) as sub-
19	section (a);
20	(C) by redesignating paragraph (5) of sub-
21	section (a) (as so redesignated) as subsection (b);
22	and
23	(D) by amending the heading for the section
24	to read as follows:

1	"CERTAIN USES OF FUNDS".
2	(2) Cross-reference.—Section 464F of the
3	Public Health Service Act (42 U.S.C. 285m-6) is
4	amended by striking "section 408(b)(1)" and insert-
5	ing "section 408(a)(1)".
6	SEC. 404. STUDY OF ENVIRONMENTAL AND OTHER RISKS
7	CONTRIBUTING TO INCIDENCE OF BREAST
8	CANCER.
9	(a) Requirement of Study.—
10	(1) In general.—The Director of the National
11	Cancer Institute (in this section referred to as the
12	"Director"), in collaboration with the Director of the
13	National Institute of Environmental Health Sciences,
14	shall conduct a case-controlled study to assess biologi-
15	cal markers of environmental and other risk factors
16	contributing to the incidence of breast cancer in—
17	(A) the Counties of Nassau and Suffolk, in
18	the State of New York; and
19	(B) the 2 counties in the northeastern Unit-
20	ed States that, as identified in the report speci-
21	fied in paragraph (2), had the highest age-ad-
22	justed mortality rate of such cancer that reflected
23	not less than 30 deaths during the 5-year period
24	for which findings are made in the report.

1	(2) RELEVANT REPORT.—The report referred to
2	in paragraph $(1)(B)$ is the report of the findings
3	made in the study entitled ''Survival, Epidemiology,
4	and End Results'', relating to cases of cancer during
5	the years 1983 through 1987.
6	(b) Certain Elements of Study.—Activities of the
7	Director in carrying out the study under subsection (a)
8	shall include the use of a geographic system to evaluate the
9	current and past exposure of individuals, incuding direct
10	monitoring and cumulative estimates of exposure, to—
11	(1) contaminated drinking water;
12	(2) sources of indoor and ambient air pollution,
13	including emissions from aircraft;
14	(3) electromagnetic fields;
15	(4) pesticides and other toxic chemicals;
16	(5) hazardous and municipal waste; and
17	(6) such other factors as the Director determines
18	to be appropriate.
19	(c) Report.—Not later than 30 months after the date
20	of the enactment of this Act, the Director shall complete the
21	study required in subsection (a) and submit to the Commit-
22	tee on Energy and Commerce of the House of Representa-
23	tives, and to the Committee on Labor and Human Re-
24	sources of the Senate, a report describing the findings made
25	as a result of the study.

1	(d) Funding.—Of the amounts appropriated for fiscal
2	years 1994 and 1995 for the National Institute of Environ-
3	mental Health Sciences and the National Cancer Institute,
4	the Director of the National Institutes of Health shall make
5	available amounts for carrying out the study required in
6	subsection (a).
7	TITLE V—NATIONAL HEART,
8	LUNG, AND BLOOD INSTITUTE
9	SEC. 501. EDUCATION AND TRAINING.
10	Section 421(b) of the Public Health Service Act (42
11	U.S.C. 285b-3(b)) is amended—
12	(1) in paragraph (3), by striking "and" after the
13	semicolon at the end;
14	(2) in paragraph (4), by striking the period at
15	the end and inserting "; and"; and
16	(3) by inserting after paragraph (4) the follow-
17	ing new paragraph:
18	"(5) shall, in consultation with the advisory
19	council for the Institute, conduct appropriate intra-
20	mural training and education programs, including
21	continuing education and laboratory and clinical re-
22	search training programs.''.

1	SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIO-
2	VASCULAR DISEASES.
3	Section 422(a)(1) of the Public Health Service Act (42
4	U.S.C. 285b-4(a)(1)) is amended—
5	(1) in subparagraph (B), by striking "and" at
6	the end;
7	(2) in subparagraph (C), by striking the period
8	and inserting "; and"; and
9	(3) by adding at the end thereof the following
10	new subparagraph:
11	"(D) three centers for basic and clinical research
12	into, training in, and demonstration of, advanced di-
13	agnostic, prevention, and treatment (including genetic
14	studies, intrauterine environment studies, postnatal
15	studies, heart arrhythmias, and acquired heart dis-
16	ease and preventive cardiology) for cardiovascular
17	diseases in children.''.
18	SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS.
19	Subpart 2 of part C of title IV of the Public Health
20	Service Act (42 U.S.C. 285b et seq.) is amended by adding
21	at the end the following new section:
22	"NATIONAL CENTER ON SLEEP DISORDERS
23	"SEC. 424. (a) Not later than 1 year after the date
24	of the enactment of the National Institutes of Health Revi-
25	talization Act of 1993, the Director of the Institute shall
26	establish the National Center on Sleep Disorders (in this

- 1 section referred to as the 'Center'). The Center shall be head-
- 2 ed by a director, who shall be appointed by the Director
- 3 of the Institute.
- 4 "(b) The general purpose of the Center is the conduct
- 5 and support of research, training, health information dis-
- 6 semination, and other activities with respect to sleep dis-
- 7 orders.
- 8 "(c) The Director of the Center may coordinate the ac-
- 9 tivities of the Center with similar activities of other agen-
- 10 cies of the Federal Government, including the other agencies
- 11 of the National Institutes of Health, and with similar ac-
- 12 tivities of other public entities and of private entities.".
- 13 SEC. 504. AUTHORIZATION OF APPROPRIATIONS.
- 14 Subpart 2 of part C of title IV of the Public Health
- 15 Service Act, as amended by section 503 of this Act, is
- 16 amended by adding at the end the following section:
- 17 "AUTHORIZATION OF APPROPRIATIONS
- 18 "Sec. 425. For the purpose of carrying out this sub-
- 19 part, there are authorized to be appropriated
- 20 *\$1,500,000,000* for fiscal year 1994, and such sums as may
- 21 be necessary for each of the fiscal years 1995 and 1996.".

1 TITLE VI—NATIONAL INSTITUTE

2 ON DIABETES AND DIGESTIVE

3 **AND KIDNEY DISEASES**

- 4 SEC. 601. PROVISIONS REGARDING NUTRITIONAL DIS-
- 5 ORDERS.
- 6 Subpart 3 of part C of title IV of the Public Health
- 7 Service Act (42 U.S.C. 285c et seq.) is amended by adding
- 8 at the end the following new section:
- 9 "NUTRITIONAL DISORDERS PROGRAM
- 10 "Sec. 434. (a) The Director of the Institute, in con-
- 11 sultation with the Director of NIH, shall establish a pro-
- 12 gram of conducting and supporting research, training,
- 13 health information dissemination, and other activities with
- 14 respect to nutritional disorders, including obesity.
- 15 "(b) In carrying out the program established under
- 16 subsection (a), the Director of the Institute shall conduct
- 17 and support each of the activities described in such sub-
- 18 section.
- 19 "(c) In carrying out the program established under
- 20 subsection (a), the Director of the Institute shall carry out
- 21 activities to facilitate and enhance knowledge and under-
- 22 standing of nutritional disorders, including obesity, on the
- 23 part of health professionals, patients, and the public
- 24 through the effective dissemination of information.".

1	(b) Development and Expansion of Research
2	AND TRAINING CENTERS.—Section 431 of the Public Health
3	Service Act (42 U.S.C. 285c-5) is amended—
4	(1) by redesignating subsection (d) as subsection
5	(e); and
6	(2) by inserting after subsection (c) the following
7	new subsection:
8	"(d)(1) The Director of the Institute shall, subject to
9	the extent of amounts made available in appropriations
10	Acts, provide for the development or substantial expansion
11	of centers for research and training regarding nutritional
12	disorders, including obesity.
13	"(2) The Director of the Institute shall carry out para-
14	graph (1) in collaboration with the Director of the National
15	Cancer Institute and with the Directors of such other agen-
16	cies of the National Institutes of Health as the Director of
17	NIH determines to be appropriate.
18	"(3) Each center developed or expanded under para-
19	graph (1) shall—
20	"(A) utilize the facilities of a single institution,
21	or be formed from a consortium of cooperating insti-
22	tutions, meeting such research and training qualifica-
23	tions as may be prescribed by the Director;
24	"(B) conduct basic and clinical research into the
25	cause, diagnosis, early detection, prevention, control

1	and treatment of nutritional disorders, including obe-
2	sity and the impact of nutrition and diet on child de-
3	velopment;
4	"(C) conduct training programs for physicians
5	and allied health professionals in current methods of
6	diagnosis and treatment of such diseases and com-
7	plications, and in research in such disorders; and
8	"(D) conduct information programs for physi-
9	cians and allied health professionals who provide pri-
10	mary care for patients with such disorders or com-
11	plications.''.
12	TITLE VII—NATIONAL INSTI-
13	TUTE ON ARTHRITIS AND
14	MUSCULOSKELETAL AND
15	SKIN DISEASES
16	SEC. 701. JUVENILE ARTHRITIS.
17	(a) Purpose.—Section 435 of the Public Health Serv-
18	ice Act (42 U.S.C. 285d) is amended by striking "and other
19	programs" and all that follows and inserting the following.
20	"and other programs with respect to arthritis and musculo-
21	skeletal and skin diseases (including sports-related dis-
22	orders), with particular attention to the effect of these dis-
23	eases on children.''.
24	(b) Programs.—Section 436 (42 U.S.C. 285d–1) is
25	amended—

1	(1) in subsection (a), by inserting after the sec-
2	ond sentence, the following: "The plan shall place
3	particular emphasis upon expanding research into
4	better understanding the causes and the development
5	of effective treatments for arthritis affecting chil-
6	dren.''; and
7	(2) in subsection (b)—
8	(A) by striking "and" at the end of para-
9	graph (3);
10	(B) by striking the period at the end of
11	paragraph (4) and inserting "; and"; and
12	(C) by adding at the end thereof the follow-
13	ing new paragraph:
14	"(5) research into the causes of arthritis affecting
15	children and the development, trial, and evaluation of
16	techniques, drugs and devices used in the diagnosis,
17	treatment (including medical rehabilitation), and
18	prevention of arthritis in children.".
19	(c) Centers.—Section 441 of the Public Health Serv-
20	ice Act (42 U.S.C. 286d-6) is amended by adding at the
21	end thereof the following new subsection:
22	"(f) Not later than October 1, 1994, the Director shall
23	establish a multipurpose arthritis and musculoskeletal dis-
24	ease center for the purpose of expanding the level of research
25	into the cause, diagnosis, early detection, prevention, con-

1	trol, and treatment of, and rehabilitation of children with
2	arthritis and musculoskeletal diseases.''.
3	(d) Advisory Board.—
4	(1) Title.—Section 442(a) of the Public Health
5	Service Act (42 U.S.C. 285d-7(a)) is amended by in-
6	serting after "Arthritis" the following: "and Musculo-
7	skeletal and Skin Diseases''.
8	(2) Composition.—Section 442(b) of the Public
9	Health Service Act (42 U.S.C. 285d-7(b)) is amend-
10	ed—
11	(A) in the matter preceding paragraph (1),
12	by striking "eighteen" and inserting "twenty";
13	and
14	(B) in paragraph (1)(B)—
15	(i) by striking "six" and inserting
16	"eight"; and
17	(ii) by striking ''including'' and all
18	that follows and inserting the following:
19	"including one member who is a person who
20	has such a disease, one person who is the
21	parent of an adult with such a disease, and
22	two members who are parents of children
23	with arthritis.".

1	(3) Annual report.—Section 442(j) of the Pub-
2	lic Health Service Act (42 U.S.C. 285d-7(j)) is
3	amended—
4	(1) by striking "and" at the end of paragraph
5	(3);
6	(2) by striking the period at the end of para-
7	graph (4) and inserting "; and"; and
8	(3) by adding at the end the following para-
9	graph:
10	"(5) contains recommendations for expanding
11	the Institute's funding of research directly applicable
12	to the cause, diagnosis, early detection, prevention,
13	control, and treatment of, and rehabilitation of chil-
14	dren with arthritis and musculoskeletal diseases.".
15	TITLE VIII—NATIONAL
16	INSTITUTE ON AGING
17	SEC. 801. ALZHEIMER'S DISEASE REGISTRY.
18	(a) In General.—Section 12 of Public Law 99-158
19	(99 Stat. 885) is—
20	(1) transferred to subpart 5 of part C of title IV
21	of the Public Health Service Act (42 U.S.C. 285e et
22	seq.);
23	(2) redesignated as section 445G; and
24	(3) inserted after section 445F of such Act.

1	(b) Technical and Conforming Amendments.—
2	Section 445G of the Public Health Service Act, as trans-
3	ferred and inserted by subsection (a) of this section, is
4	amended—
5	(1) by striking the section heading and all that
6	follows through ''may make a grant'' in subsection (a)
7	and inserting the following:
8	"ALZHEIMER'S DISEASE REGISTRY
9	"Sec. 445G. (a) In General.—The Director of the
10	Institute may make a grant"; and
11	(2) by striking subsection (c).
12	SEC. 802. AGING PROCESSES REGARDING WOMEN.
13	Subpart 5 of part C of title IV of the Public Health
14	Service Act, as amended by section 801 of this Act, is
15	amended by adding at the end the following new section:
16	"AGING PROCESSES REGARDING WOMEN
17	"SEC. 445H. The Director of the Institute, in addition
18	to other special functions specified in section 444 and in
19	cooperation with the Directors of the other national research
20	institutes and agencies of the National Institutes of Health,
21	shall conduct research into the aging processes of women,
22	with particular emphasis given to the effects of menopause
23	and the physiological and behavioral changes occurring
24	during the transition from pre- to post-menopause, and into
25	the diagnosis, disorders, and complications related to aging
26	and loss of ovarian hormones in women."

1 SEC. 803. AUTHORIZATION OF APPROPRIATIONS.

- 2 Subpart 5 of part C of title IV of the Public Health
- 3 Service Act, as amended by section 802 of this Act, is
- 4 amended by adding at the end the following new section:
- 5 "AUTHORIZATION OF APPROPRIATIONS
- 6 "Sec. 4451. For the purpose of carrying out this sub-
- 7 part, there are authorized to be appropriated \$500,000,000
- 8 for fiscal year 1994, and such sums as may be necessary
- 9 for each of the fiscal years 1995 and 1996.".

10 SEC. 804. CONFORMING AMENDMENT.

- 11 Section 445C of the Public Health Service Act (42
- 12 U.S.C. 285e-5), as amended by section 9 of Public Law
- 13 102-507 (106 Stat. 3287), is amended—
- 14 (1) in subsection (b)(1), in the first sentence, by
- inserting after "Council" the following: "on Alz-
- 16 heimer's Disease (hereafter in this section referred to
- 17 as the 'Council')''; and
- 18 (2) by adding at the end the following new sub-
- 19 *section:*
- 20 "(e) For purposes of this section, the term 'Council on
- 21 Alzheimer's Disease' means the council established in sec-
- 22 tion 911(a) of Public Law 99–660.".

TITLE IX—NATIONAL INSTITUTE

2 **OF ALLERGY AND INFEC**-

3 **TIOUS DISEASES**

- 4 SEC. 901. TROPICAL DISEASES.
- 5 Section 446 of the Public Health Service Act (42)
- 6 U.S.C. 285f) is amended by inserting before the period the
- 7 following: ", including tropical diseases".
- 8 SEC. 902. CHRONIC FATIGUE SYNDROME.
- 9 (a) Research Centers.—Subpart 6 of part C of title
- 10 IV of the Public Health Service Act (42 U.S.C. 285f) is
- 11 amended by adding at the end the following new section:
- 12 "RESEARCH CENTERS REGARDING CHRONIC FATIGUE
- 13 SYNDROME
- 14 "Sec. 447. (a) The Director of the Institute, after con-
- 15 sultation with the advisory council for the Institute, may
- 16 make grants to, or enter into contracts with, public or non-
- 17 profit private entities for the development and operation of
- 18 centers to conduct basic and clinical research on chronic
- 19 fatigue syndrome.
- 20 "(b) Each center assisted under this section shall use
- 21 the facilities of a single institution, or be formed from a
- 22 consortium of cooperating institutions, meeting such re-
- 23 quirements as may be prescribed by the Director of the In-
- 24 stitute.".

1	(D) EXTRAMURAL STUDY SECTION.—NOT later than C
2	months after the date of enactment of this Act, the Secretary
3	of Health and Human Services shall establish an extra-
4	mural study section for chronic fatigue syndrome research
5	(c) Representatives.—The Secretary of Health and
6	Human Services, acting through the Director of the Na-
7	tional Institutes of Health, shall ensure that appropriate
8	individuals with expertise in chronic fatigue syndrome of
9	neuromuscular diseases and representative of a variety of
10	disciplines and fields within the research community are
11	appointed to appropriate National Institutes of Health ad-
12	visory committees and boards.
13	TITLE X—NATIONAL INSTITUTE
14	OF CHILD HEALTH AND
15	HUMAN DEVELOPMENT
16	Subtitle A—Research Centers With
17	Respect to Contraception and
18	Research Centers With Respect
19	to Infertility
20	SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CEN
21	TERS.
22	Subpart 7 of part C of title IV of the Public Health
23	Service Act, as amended by section 3 of Public Law 101-
24	613, is amended by adding at the end the following new
25	section:

1	"RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION
2	AND INFERTILITY
3	"Sec. 452A. (a) The Director of the Institute, after
4	consultation with the advisory council for the Institute,
5	shall make grants to, or enter into contracts with, public
6	or nonprofit private entities for the development and oper-
7	ation of centers to conduct activities for the purpose of im-
8	proving methods of contraception and centers to conduct ac-
9	tivities for the purpose of improving methods of diagnosis
10	and treatment of infertility.
11	"(b) In carrying out subsection (a), the Director of the
12	Institute shall, subject to the extent of amounts made avail-
13	able in appropriations Acts, provide for the establishment
14	of three centers with respect to contraception and for two
15	centers with respect to infertility.
16	"(c)(1) Each center assisted under this section shall,
17	in carrying out the purpose of the center involved—
18	"(A) conduct clinical and other applied research,
19	including—
20	"(i) for centers with respect to contracep-
21	tion, clinical trials of new or improved drugs
22	and devices for use by males and females (in-
23	cluding barrier methods); and
24	"(ii) for centers with respect to infertility,
25	clinical trials of new or improved drugs and de-

1	vices for the diagnosis and treatment of infertil-
2	ity in males and females;
3	"(B) develop protocols for training physicians,
4	scientists, nurses, and other health and allied health
5	professionals;
6	"(C) conduct training programs for such indi-
7	viduals;
8	"(D) develop model continuing education pro-
9	grams for such professionals; and
10	"(E) disseminate information to such profes-
11	sionals and the public.
12	"(2) A center may use funds provided under subsection
13	(a) to provide stipends for health and allied health profes-
14	sionals enrolled in programs described in subparagraph (C)
15	of paragraph (1), and to provide fees to individuals serving
16	as subjects in clinical trials conducted under such para-
17	graph.
18	"(d) The Director of the Institute shall, as appropriate,
19	provide for the coordination of information among the cen-
20	ters assisted under this section.
21	"(e) Each center assisted under subsection (a) shall use
22	the facilities of a single institution, or be formed from a
23	consortium of cooperating institutions, meeting such re-
24	quirements as may be prescribed by the Director of the In-
25	stitute.

1	"(f) Support of a center under subsection (a) may be
2	for a period not exceeding 5 years. Such period may be ex-
3	tended for one or more additional periods not exceeding 5
4	years if the operations of such center have been reviewed
5	by an appropriate technical and scientific peer review
6	group established by the Director and if such group has rec-
7	ommended to the Director that such period should be ex-
8	tended.
9	"(g) For the purpose of carrying out this section, there
10	are authorized to be appropriated \$30,000,000 for fiscal
11	year 1994, and such sums as may be necessary for each
12	of the fiscal years 1995 and 1996.".
13	SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH
14	WITH RESPECT TO CONTRACEPTION AND IN-
14 15	WITH RESPECT TO CONTRACEPTION AND IN- FERTILITY.
15	FERTILITY.
15 16	FERTILITY. Part G of title IV of the Public Health Service Act,
15 16 17	FERTILITY. Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended
15 16 17 18	FERTILITY. Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section:
15 16 17 18 19	FERTILITY. Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section: "LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
15 16 17 18 19 20	FERTILITY. Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section: "LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY
15 16 17 18 19 20 21 22	FERTILITY. Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section: "LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY "Sec. 487B. (a) The Secretary, in consultation with
15 16 17 18 19 20 21 22	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section: "LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY" "Sec. 487B. (a) The Secretary, in consultation with the Director of the National Institute of Child Health and
15 16 17 18 19 20 21 22 23	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section: "LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY "SEC. 487B. (a) The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program of entering

- 1 tion, or with respect to infertility, in consideration of the
- 2 Federal Government agreeing to repay, for each year of such
- 3 service, not more than \$20,000 of the principal and interest
- 4 of the educational loans of such health professionals.
- 5 "(b) The provisions of sections 338B, 338C, and 338E
- 6 shall apply to the program established in subsection (a) to
- 7 the same extent and in the same manner as such provisions
- 8 apply to the National Health Service Corps Loan Repay-
- 9 ment Program established in subpart III of part D of title
- 10 111.
- 11 "(c) Amounts appropriated for carrying out this sec-
- 12 tion shall remain available until the expiration of the sec-
- 13 ond fiscal year beginning after the fiscal year for which
- 14 the amounts were appropriated.".

15 Subtitle B—Program Regarding

16 **Obstetrics and Gynecology**

- 17 SEC. 1011. ESTABLISHMENT OF PROGRAM.
- 18 Subpart 7 of part C of title IV of the Public Health
- 19 Service Act, as amended by section 1001 of this Act, is
- 20 amended by adding at the end the following new section:
- 21 "PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY
- 22 "Sec. 452B. The Director of the Institute shall estab-
- 23 lish and maintain within the Institute an intramural lab-
- 24 oratory and clinical research program in obstetrics and
- 25 gynecology.".

1	Subtitle C—Child Health Research
2	Centers
3	SEC. 1021. ESTABLISHMENT OF CENTERS.
4	Subpart 7 of part C of title IV of the Public Health
5	Service Act, as amended by section 1011 of this Act, is
6	amended by adding at the end the following new section:
7	"CHILD HEALTH RESEARCH CENTERS
8	"Sec. 452C. The Director of the Institute shall develop
9	and support centers for conducting research with respect to
10	child health. Such centers shall give priority to the expedi-
11	tious transfer of advances from basic science to clinical ap-
12	plications and improving the care of infants and children.".
13	Subtitle D—Study Regarding
14	Adolescent Health
15	SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.
16	Subpart 7 of part C of title IV of the Public Health
17	Service Act, as amended by section 1021 of this Act, is
18	amended by adding at the end the following new section:
19	"PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT
20	HEALTH
21	"Sec. 452D. (a) In General.—Not later than October
22	1, 1993, the Director of the Institute shall commence a study
23	for the purpose of providing information on the general
24	health and well-being of adolescents in the United States.

1	including, with respect to such adolescents, information
2	on—
3	"(1) the behaviors that promote health and the
4	behaviors that are detrimental to health; and
5	"(2) the influence on health of factors particular
6	to the communities in which the adolescents reside.
7	"(b) Design of Study.—
8	"(1) In general.—The study required in sub-
9	section (a) shall be a longitudinal study in which a
10	substantial number of adolescents participate as sub-
11	jects. With respect to the purpose described in such
12	subsection, the study shall monitor the subjects
13	throughout the period of the study to determine the
14	health status of the subjects and any change in such
15	status over time.
16	"(2) Population-specific analyses.—The
17	study required in subsection (a) shall be conducted
18	with respect to the population of adolescents who are
19	female, the population of adolescents who are male,
20	various socioeconomic populations of adolescents, and
21	various racial and ethnic populations of adolescents.

The study shall be designed and conducted in a man-

ner sufficient to provide for a valid analysis of wheth-

er there are significant differences among such popu-

lations in health status and whether and to what ex-

22

23

24

25

1	tent any such differences are due to factors particular
2	to the populations involved.
3	"(c) Coordination With Women's Health Initia-
4	TIVE.—With respect to the national study of women being
5	conducted by the Secretary and known as the Women's
6	Health Initiative, the Secretary shall ensure that such study
7	is coordinated with the component of the study required in
8	subsection (a) that concerns adolescent females, including
9	coordination in the design of the 2 studies.".
10	TITLE XI—NATIONAL EYE
11	INSTITUTE
12	SEC. 1101. CLINICAL RESEARCH ON DIABETES EYE CARE.
13	(a) In General.—Subpart 9 of part C of title IV of
14	the Public Health Service Act (42 U.S.C. 285i) is amended
15	by adding at the end the following new section:
16	"CLINICAL RESEARCH ON EYE CARE AND DIABETES
17	"Sec. 456. (a) Program of Grants.—The Director
18	of the Institute, in consultation with the advisory council
19	for the Institute, may award not more than three grants
20	for the establishment and support of centers for clinical re-
21	search on eye care for individuals with diabetes.
22	"(b) Authorized Expenditures.—The purposes for
23	which a grant under subsection (a) may be expended in-
24	clude equipment for the research described in such sub-
25	section and the construction and modernization of facilities
26	for such research "

1	(b) Conforming Amendment.—Section 455 of the
2	Public Health Service Act (42 U.S.C. 285i) is amended in
3	the second sentence by striking "The Director" and insert-
4	ing "Subject to section 456, the Director".
5	TITLE XII—NATIONAL INSTI-
6	TUTE OF NEUROLOGICAL DIS-
7	ORDERS AND STROKE
8	SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.
9	Subpart 10 of part C of title IV of the Public Health
10	Service Act (42 U.S.C. 285j et seq.) is amended by adding
11	at the end the following new section:
12	"RESEARCH ON MULTIPLE SCLEROSIS
13	"Sec. 460. The Director of the Institute shall conduct
14	and support research on multiple sclerosis, especially re-
15	search on effects of genetics and hormonal changes on the
16	progress of the disease.".
17	TITLE XIII—NATIONAL INSTI-
18	TUTE OF ENVIRONMENTAL
19	HEALTH SCIENCES
20	SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TEST-
21	ING PROGRAM.
22	(a) In General.—Subpart 12 of part C of title IV
23	of the Public Health Service Act (42 U.S.C. 2851) is amend-
24	ed by adding at the end the following new section:

1	"APPLIED TOXICOLOGICAL RESEARCH AND TESTING
2	PROGRAM
3	"Sec. 463A. (a) There is established within the Insti-
4	tute a program for conducting applied research and testing
5	regarding toxicology, which program shall be known as the
6	Applied Toxicological Research and Testing Program.
7	"(b) In carrying out the program established under
8	subsection (a), the Director of the Institute shall, with re-
9	spect to toxicology, carry out activities—
10	"(1) to expand knowledge of the health effects of
11	environmental agents;
12	"(2) to broaden the spectrum of toxicology infor-
13	mation that is obtained on selected chemicals;
14	"(3) to develop and validate assays and proto-
15	cols, including alternative methods that can reduce or
16	eliminate the use of animals in acute or chronic safe-
17	ty testing;
18	"(4) to establish criteria for the validation and
19	regulatory acceptance of alternative testing and to
20	recommend a process through which scientifically
21	validated alternative methods can be accepted for reg-
22	ulatory use;
23	"(5) to communicate the results of research to
24	government agencies, to medical, scientific, and regu-
25	latory communities, and to the public; and

1	"(6) to integrate related activities of the Depart-
2	ment of Health and Human Services.".
3	(b) Technical Amendment.—Section 463 of the Pub-
4	lic Health Service Act (42 U.S.C. 2851) is amended by in-
5	serting after "Sciences" the following: "(hereafter in this
6	subpart referred to as the 'Institute')''.
7	SEC. 1302. STUDY OF ENVIRONMENTAL AND OTHER RISKS
8	CONTRIBUTING TO INCIDENCE OF BREAST
9	AND PROSTATE CANCER.
10	(a) In General.—The Director of the National Insti-
11	tute of Environmental Health Sciences (in this section re-
12	ferred to as the "Director"), in collaboration with the Direc-
13	tor of the National Cancer Institute, shall conduct a case-
14	controlled study to assess biological markers of environ-
15	mental and other risk factors contributing to the incidence
16	of breast and prostate cancer in the Counties of Nassau and
17	Suffolk, in the State of New York.
18	(b) Certain Elements of Study.—Activities of the
19	Director in carrying out the study under subsection (a)
20	shall include the use of a geographic system to evaluate the
21	current and past exposure of individuals, including direct
22	monitoring and cumulative estimates of exposure, to—
23	(1) contaminated drinking water;
24	(2) sources of indoor and ambient air pollution,
25	including emissions from aircraft;

1	(3) electromagnetic fields;
2	(4) pesticides and other toxic chemicals;
3	(5) hazardous and municipal waste; and
4	(6) such other factors as the Director determines
5	to be appropriate.
6	(c) Report.—Not later than 24 months after the date
7	of the enactment of this Act, the Director shall complete the
8	study required in subsection (a) and submit to the Commit-
9	tee on Energy and Commerce of the House of Representa-
10	tives, and to the Committee on Labor and Human Re-
11	sources of the Senate, a report describing the findings made
12	as a result of the study.
13	(d) Funding.—Of the amounts appropriated for fiscal
14	years 1994 and 1995 for the National Institute of Environ-
15	mental Health Sciences and the National Cancer Institute,
16	the Director of the National Institutes of Health shall make
17	available amounts for carrying out the study required in
18	subsection (a).
19	TITLE XIV—NATIONAL LIBRARY
20	OF MEDICINE
21	Subtitle A—General Provisions
22	SEC. 1401. ADDITIONAL AUTHORITIES.
23	(a) In General.—Section 465(b) of the Public Health
24	Service Act (42 U.S.C. 286(b)) is amended—

1	(1) by striking "and" after the semicolon at the
2	end of paragraph (5);
3	(2) by redesignating paragraph (6) as para-
4	graph (8); and
5	(3) by inserting after paragraph (5) the follow-
6	ing new paragraphs:
7	"(6) publicize the availability from the Library
8	of the products and services described in any of para-
9	graphs (1) through (5);
10	"(7) promote the use of computers and tele-
11	communications by health professionals (including
12	health professionals in rural areas) for the purpose of
13	improving access to biomedical information for health
14	care delivery and medical research; and".
15	(b) Limitation Regarding Grants.—Section
16	474(b)(2) of the Public Health Service Act (42 U.S.C. 286b-
17	S(b)(2)) is amended by striking "\$750,000" and inserting
18	<i>``\$1,000,000``.</i>
19	(c) Technical and Conforming Amendments.—
20	(1) Repeal of Certain Authority.—Section
21	215 of the Department of Health and Human Serv-
22	ices Appropriations Act, 1988, as contained in section
23	101(h) of Public Law 100–202 (101 Stat. 1329–275),
24	is repealed.

- 112 (2) Applicability of certain new author-1 2 ITY.—With respect to the authority established for the National Library of Medicine in section 465(b)(6) of 3 the Public Health Service Act, as added by subsection (a) of this section, such authority shall be effective as 5 if the authority had been established on December 22, 6 7 1987. SEC. 1402. AUTHORIZATION OF APPROPRIATIONS. 9 (a) Establishment of Single Authorization.—
- Subpart 1 of part D of title IV of the Public Health Service
- Act (42 U.S.C. 286 et seq.) is amended by adding at the
- end the following section:
- 13 "AUTHORIZATION OF APPROPRIATIONS
- "SEC. 468. (a) For the purpose of carrying out this 14
- part, there are authorized to be appropriated \$150,000,000
- for fiscal year 1994, and such sums as may be necessary
- for each of the fiscal years 1995 and 1996.
- "(b) Amounts appropriated under subsection (a) and 18
- made available for grants or contracts under any of sections
- 472 through 476 shall remain available until the end of
- the fiscal year following the fiscal year for which the 21
- 22 amounts were appropriated.".
- 23 (b) Conforming Amendments.—Part D of title IV
- of the Public Health Service Act (42 U.S.C. 286 et seq.)
- is amended by striking section 469 and section 478(c).

1	Subtitle B—Financial Assistance
2	SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR
3	DEVELOPMENT OF EDUCATION TECH-
4	NOLOGIES.
5	Section 473 of the Public Health Service Act (42
6	U.S.C. 286b-4) is amended by adding at the end the follow-
7	ing new subsection:
8	"(c)(1) The Secretary shall make grants to public or
9	nonprofit private institutions for the purpose of carrying
10	out projects of research on, and development and dem-
11	onstration of, new education technologies.
12	"(2) The purposes for which a grant under paragraph
13	(1) may be made include projects concerning—
14	"(A) computer-assisted teaching and testing of
15	clinical competence at health professions and research
16	institutions;
17	"(B) the effective transfer of new information
18	from research laboratories to appropriate clinical ap-
19	plications;
20	"(C) the expansion of the laboratory and clinical
21	uses of computer-stored research databases; and
22	"(D) the testing of new technologies for training
23	health care professionals.

1	"(3) The Secretary may not make a grant under para-
2	graph (1) unless the applicant for the grant agrees to make
3	the projects available with respect to—
4	"(A) assisting in the training of health profes-
5	sions students; and
6	"(B) enhancing and improving the capabilities
7	of health professionals regarding research and teach-
8	ing.".
9	Subtitle C—National Information
10	Center on Health Services Re-
11	search and Health Care Tech-
12	nology
13	SEC. 1421. ESTABLISHMENT OF CENTER.
14	Part D of title IV of the Public Health Service Act
15	(42 U.S.C. 286 et seq.) is amended by adding at the end
16	the following new subpart:
17	"Subpart 4—National Information Center on Health
18	Services Research and Health Care Technology
19	"NATIONAL INFORMATION CENTER
20	"SEC. 478A. (a) There is established within the Li-
21	brary an entity to be known as the National Information
22	Center on Health Services Research and Health Care Tech-
23	nology (in this section referred to as the 'Center').
24	"(b) The purpose of the Center is the collection, storage,
25	analysis, retrieval, and dissemination of information on

- 1 health services research, clinical practice guidelines, and on
- 2 health care technology, including the assessment of such
- 3 technology. Such purpose includes developing and main-
- 4 taining data bases and developing and implementing meth-
- 5 ods of carrying out such purpose.
- 6 "(c) The Director of the Center shall ensure that infor-
- 7 mation under subsection (b) concerning clinical practice
- 8 guidelines is collected and maintained electronically and in
- 9 a convenient format. Such Director shall develop and pub-
- 10 lish criteria for the inclusion of practice guidelines and
- 11 technology assessments in the information center database.
- 12 "(d) The Secretary, acting through the Center, shall
- 13 coordinate the activities carried out under this section
- 14 through the Center with related activities of the Adminis-
- 15 trator for Health Care Policy and Research.".

16 SEC. 1422. CONFORMING PROVISIONS.

- 17 (a) In General.—Section 903 of the Public Health
- 18 Service Act, as amended by section 3 of Public Law 102-
- 19 410 (106 Stat. 2094), is amended by amending subsection
- 20 (e) to read as follows:
- 21 "(e) REQUIRED INTERAGENCY AGREEMENT.—The Ad-
- 22 ministrator and the Director of the National Library of
- 23 Medicine shall enter into an agreement providing for the
- 24 implementation of section 478A.".

1	(b) Rule of Construction.—The amendments made
2	by section 3 of Public Law 102–410 (106 Stat. 2094), by
3	section 1421 of this Act, and by subsection (a) of this section
4	may not be construed as terminating the information center
5	on health care technologies and health care technology as-
6	sessment established under section 904 of the Public Health
7	Service Act, as in effect on the day before the date of the
8	enactment of Public Law 102-410. Such center shall be con-
9	sidered to be the center established in section 478A of the
10	Public Health Service Act, as added by section 1421 of this
11	Act, and shall be subject to the provisions of such section
12	478A.
13	TITLE XV—OTHER AGENCIES OF
14	NATIONAL INSTITUTES OF
15	HEALTH
16	Subtitle A—Division of Research
17	
1 Q	Resources
10	<u>_</u>
	Resources
19 20	Resources SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL
19 20	Resources SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES.
19 20	Resources SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES. Title IV of the Public Health Service Act (42 U.S.C.
19 20 21	Resources SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES. Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—
19 20 21 22	Resources SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES. Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended— (1) in section 401(b)(2)(B), by amending such

1	(2) in part E—
2	(A) in the heading for subpart 1, by strik-
3	ing "Division of" and inserting "National Cen-
4	ter for";
5	(B) in section 479, by striking "the Divi-
6	sion of Research Resources' and inserting the
7	following: "the National Center for Research Re-
8	sources (hereafter in this subpart referred to as
9	the 'Center')'';
10	(C) in sections 480 and 481, by striking
11	"the Division of Research Resources" each place
12	such term appears and inserting "the Center";
13	and
14	(D) in sections 480 and 481, as amended by
15	subparagraph (C), by striking "the Division"
16	each place such term appears and inserting "the
17	Center".
18	SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FA-
19	CILITIES.
20	Subpart 1 of part E of title IV of the Public Health
21	Service Act (42 U.S.C. 287 et seq.) is amended by adding
22	at the end the following new section:
23	"BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES
24	"Sec. 481A. (a) Modernization and Construction
25	OF FACILITIES —

1	"(1) In general.—The Director of NIH, acting
2	through the Director of the Center, may make grants
3	to public and nonprofit private entities to expand, re-
4	model, renovate, or alter existing research facilities or
5	construct new research facilities, subject to the provi-
6	sions of this section.
7	"(2) Construction and cost of construc-
8	TION.—For purposes of this section, the terms
9	'construction' and 'cost of construction' include the
10	construction of new buildings and the expansion, ren-
11	ovation, remodeling, and alteration of existing build-
12	ings, including architects' fees, but do not include the
13	cost of acquisition of land or off-site improvements.
14	"(b) Scientific and Technical Review Boards
15	for Merit-Based Review of Proposals.—
16	"(1) In general; approval as precondition
17	TO GRANTS.—
18	"(A) There is established within the Center
19	a Scientific and Technical Review Board on
20	Biomedical and Behavioral Research Facilities
21	(hereafter referred to in this section as the
22	'Board').
23	"(B) The Director of the Center may ap-
24	prove an application for a grant under
25	subsection (a) only if the Board has under para-

1	graph (2) recommended the application for ap-
2	proval.
3	"(2) Duties.—
4	"(A) The Board shall provide advice to the
5	Director of the Center and the advisory council
6	established under section 480 (hereafter in this
7	section referred to as the 'Advisory Council') on
8	carrying out this section.
9	"(B) In carrying out subparagraph (A), the
10	Board shall make a determination of the merit
11	of each application submitted for a grant under
12	subsection (a), after consideration of the require-
13	ments established in subsection (c), and shall re-
14	port the results of the determination to the Direc-
15	tor of the Center and the Advisory Council. Such
16	determinations shall be conducted in a manner
17	consistent with procedures established under sec-
18	tion 492.
19	"(C) In carrying out subparagraph (A), the
20	Board shall, in the case of applications rec-
21	ommended for approval, make recommendations
22	to the Director and the Advisory Council on the
23	amount that should be provided in the grant.
24	"(D) In carrying out subparagraph (A), the
25	Board shall prepare an annual report for the Di-

1	rector of the Center and the Advisory Council de-
2	scribing the activities of the Board in the fiscal
3	year for which the report is made. Each such re-
4	port shall be available to the public, and shall—
5	"(i) summarize and analyze expendi-
6	tures made under this section;
7	"(ii) provide a summary of the types,
8	numbers, and amounts of applications that
9	were recommended for grants under sub-
10	section (a) but that were not approved by
11	the Director of the Center; and
12	"(iii) contain the recommendations of
13	the Board for any changes in the adminis-
14	tration of this section.
15	"(3) Membership.—
16	"(A) Subject to subparagraph (B), the
17	Board shall be composed of 9 appointed mem-
18	bers, and such ex officio members as the Director
19	of the Center determines to be appropriate.
20	"(B) Not more than 3 individuals who are
21	officers or employees of the Federal Government
22	may serve as members of the Board.
23	"(4) Certain requirements regarding mem-
24	BERSHIP.—In selecting individuals for membership
25	on the Board, the Director of the Center shall ensure

1	that the members are individuals who, by virtue of
2	their training or experience, are eminently qualified
3	to perform peer review functions. In selecting such in-
4	dividuals for such membership, the Director of the
5	Center shall ensure that the members of the Board col-
6	lectively—
7	"(A) are experienced in the planning, con-
8	struction, financing, and administration of enti-
9	ties that conduct biomedical or behavioral re-
10	search sciences;
11	"(B) are knowledgeable in making deter-
12	minations of the need of entities for biomedical
13	or behavioral research facilities, including such
14	facilities for the dentistry, nursing, pharmacy,
15	and allied health professions;
16	"(C) are knowledgeable in evaluating the
17	relative priorities for applications for grants
18	under subsection (a) in view of the overall re-
19	search needs of the United States; and
20	"(D) are experienced with emerging centers
21	of excellence, as described in subsection (c)(3).
22	"(5) Certain authorities.—
23	"(A) In carrying out paragraph (2), the
24	Board may convene workshops and conferences,

1	and collect data as the Board considers appro-
2	priate.
3	"(B) In carrying out paragraph (2), the
4	Board may establish subcommittees within the
5	Board. Such subcommittees may hold meetings
6	as determined necessary to enable the sub-
7	committee to carry out its duties.
8	"(6) TERMS.—
9	"(A) Except as provided in subparagraph
10	(B), each appointed member of the Board shall
11	hold office for a term of 4 years. Any member
12	appointed to fill a vacancy occurring prior to
13	the expiration of the term for which such mem-
14	ber's predecessor was appointed shall be ap-
15	pointed for the remainder of the term of the
16	predecessor.
17	"(B) Of the initial members appointed to
18	the Board (as specified by the Director of the
19	Center when making the appointments)—
20	"(i) 3 shall hold office for a term of 3
21	years;
22	"(ii) 3 shall hold office for a term of 2
23	years; and
24	"(iii) 3 shall hold office for a term of
25	1 year.

1	"(C) No member is eligible for reappoint-
2	ment to the Board until 1 year has elapsed after
3	the end of the most recent term of the member.
4	"(7) Compensation.—Members of the Board
5	who are not officers or employees of the United States
6	shall receive for each day the members are engaged in
7	the performance of the functions of the Board com-
8	pensation at the same rate received by members of
9	other national advisory councils established under
10	this title.
11	"(c) Requirements for Grants.—
12	"(1) In general.—The Director of the Center
13	may make a grant under subsection (a) only if the
14	applicant for the grant meets the following conditions:
15	"(A) The applicant is determined by such
16	Director to be competent to engage in the type of
17	research for which the proposed facility is to be
18	constructed.
19	"(B) The applicant provides assurances sat-
20	isfactory to the Director that—
21	"(i) for not less than 20 years after
22	completion of the construction, the facility
23	will be used for the purposes of research for
24	which it is to be constructed;

1	''(ii) sufficient funds will be available
2	to meet the non-Federal share of the cost of
3	constructing the facility;
4	"(iii) sufficient funds will be available,
5	when construction is completed, for the ef-
6	fective use of the facility for the research for
7	which it is being constructed; and
8	"(iv) the proposed construction will ex-
9	pand the applicant's capacity for research,
10	or is necessary to improve or maintain the
11	quality of the applicant's research.
12	"(C) The applicant meets reasonable quali-
13	fications established by the Director with respect
14	to—
15	"(i) the relative scientific and technical
16	merit of the applications, and the relative
17	effectiveness of the proposed facilities, in ex-
18	panding the capacity for biomedical or be-
19	havioral research and in improving the
20	quality of such research;
21	"(ii) the quality of the research or
22	training, or both, to be carried out in the
23	facilities involved;
24	"(iii) the need of the applicant for such
25	facilities in order to maintain or expand

1	the applicant's research and training mis-
2	sion;
3	"(iv) the congruence of the research ac-
4	tivities to be carried out within the facility
5	with the research and investigator man-
6	power needs of the United States; and
7	"(v) the age and condition of existing
8	research facilities and equipment.
9	"(D) The applicant has demonstrated a
10	commitment to enhancing and expanding the re-
11	search productivity of the applicant.
12	"(2) Consideration of certain factors.—In
13	making grants under subsection (a), the Director of
14	the Center may, in addition to the requirements es-
15	tablished in paragraph (1), consider the following fac-
16	tors:
17	"(A) To what extent the applicant has the
18	capacity to broaden the scope of research and re-
19	search training programs of the applicant by
20	promoting—
21	''(i) interdisciplinary research;
22	''(ii) research on emerging technologies,
23	including those involving novel analytical
24	techniques or computational methods; or

1	"(iii) other novel research mechanisms
2	or programs.
3	"(B) To what extent the applicant has
4	broadened the scope of research and research
5	training programs of qualified institutions by
6	promoting genomic research with an emphasis
7	on interdisciplinary research, including research
8	related to pediatric investigations.
9	"(3) Institutions of emerging excel-
10	LENCE.—Of the amounts appropriated under sub-
11	section (h) for a fiscal year, the Director of the Center
12	shall make available 25 percent for grants under sub-
13	section (a) to applicants that, in addition to meeting
14	the requirements established in paragraph (1), have
15	demonstrated emerging excellence in biomedical or be-
16	havioral research, as follows:
17	"(A) The applicant has a plan for research
18	or training advancement and possesses the abil-
19	ity to carry out the plan.
20	"(B) The applicant carries out research and
21	research training programs that have a special
22	relevance to a problem, concern, or unmet health
23	need of the United States.
24	"(C) The applicant has been productive in
25	research or research development and training.

1	"(D) The applicant—
2	"(i) has been designated as a center of
3	excellence under section 739;
4	''(ii) is located in a geographic area a
5	significant percentage of whose population
6	has a health-status deficit, and the appli-
7	cant provides health services to such popu-
8	lation; or
9	"(iii) is located in a geographic area
10	in which a deficit in health care technology,
11	services, or research resources may adversely
12	affect health status of the population of the
13	area in the future, and the applicant is car-
14	rying out activities with respect to protect-
15	ing the health status of such population.
16	"(d) Requirement of Application.—The Director
17	of the Center may make a grant under subsection (a) only
18	if an application for the grant is submitted to the Director
19	and the application is in such form, is made in such man-
20	ner, and contains such agreements, assurances, and infor-
21	mation as the Director determines to be necessary to carry
22	out this section.
23	"(e) Amount of Grant; Payments.—
24	"(1) Amount.—The amount of any grant
25	awarded under subsection (a) shall be determined by

1	the Director of the Center, except that such amount	
2	shall not exceed—	
3	"(A) 50 percent of the necessary cost of the	
4	construction of a proposed facility as determined	
5	by the Director; or	
6	"(B) in the case of a multipurpose facility,	
7	40 percent of that part of the necessary cost of	
8	construction that the Director determines to be	
9	proportionate to the contemplated use of the fa-	
10	cility.	
11	"(2) Reservation of amounts.—On approval	
12	of any application for a grant under subsection (a),	
13	the Director of the Center shall reserve, from any ap-	
14	propriation available therefore, the amount of such	
15	grant, and shall pay such amount, in advance or by	
16	way of reimbursement, and in such installments con-	
17	sistent with the construction progress, as the Director	
18	may determine appropriate. The reservation of the	
19	Director of any amount by the Director under this	
20	paragraph may be amended by the Director, either on	
21	the approval of an amendment of the application or	
22	on the revision of the estimated cost of construction	
23	of the facility.	
24	"(3) Exclusion of certain costs.—In deter-	
25	mining the amount of any grant under this sub-	

1	section (a), there shall be excluded from the cost of
2	construction an amount equal to the sum of—
3	"(A) the amount of any other Federal grant
4	that the applicant has obtained, or is assured of
5	obtaining, with respect to construction that is to
6	be financed in part by a grant authorized under
7	this section; and
8	"(B) the amount of any non-Federal funds
9	required to be expended as a condition of such
10	other Federal grant.
11	"(4) Waiver of Limitations.—The limitations
12	imposed by paragraph (1) may be waived at the dis-
13	cretion of the Director for applicants meeting the con-
14	ditions described in paragraphs (1) and (2) of sub-
15	section (c).
16	"(f) Recapture of Payments.—If, not later than 20
17	years after the completion of construction for which a grant
18	has been awarded under subsection (a)—
19	"(1) the applicant or other owner of the facility
20	shall cease to be a public or nonprofit private entity,
21	or
22	"(2) the facility shall cease to be used for the re-
23	search purposes for which it was constructed (unless
24	the Director determines, in accordance with regula-

- 1 tions, that there is good cause for releasing the appli-
- 2 cant or other owner from obligation to do so);
- 3 the United States shall be entitled to recover from the appli-
- 4 cant or other owner of the facility the amount bearing the
- 5 same ratio to the current value (as determined by an agree-
- 6 ment between the parties or by action brought in the United
- 7 States District Court for the district in which such facility
- 8 is situated) of the facility as the amount of the Federal
- 9 participation bore to the cost of the construction of such
- 10 facility.
- 11 "(g) Guidelines.—Not later than 6 months after the
- 12 date of the enactment of this section, the Director of the
- 13 Center, after consultation with the Advisory Council, shall
- 14 issue guidelines with respect to grants under subsection (a).
- 15 "(h) AUTHORIZATION OF APPROPRIATIONS.—For the
- 16 purpose of carrying out this section, there are authorized
- 17 to be appropriated \$150,000,000 for fiscal year 1994, and
- 18 such sums as may be necessary for each of the fiscal years
- 19 1995 and 1996.".
- 20 SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRI-
- 21 **MATE RESEARCH CENTER.**
- 22 Subpart 1 of part E of title IV of the Public Health
- 23 Service Act, as amended by section 1502 of this Act, is
- 24 amended by adding at the end the following new section:

1	"CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH
2	ON PRIMATES
3	"Sec. 481B. (a) With respect to activities carried out
4	by the National Center for Research Resources to support
5	regional centers for research on primates, the Director of
6	NIH shall, for each of the fiscal years 1994 through 1996,
7	reserve from the amounts appropriated under section
8	481A(i) \$5,000,000 for the purpose of making awards of
9	grants and contracts to public or nonprofit private entities
10	to construct, renovate, or otherwise improve such regional
11	centers. The reservation of such amounts for any fiscal year
12	is subject to the availability of qualified applicants for such
13	awards.
14	"(b) The Director of NIH may not make a grant or
15	enter into a contract under subsection (a) unless the appli-
16	cant for such assistance agrees, with respect to the costs to
17	be incurred by the applicant in carrying out the purpose
18	described in such subsection, to make available (directly or
19	through donations from public or private entities) non-Fed-
20	eral contributions in cash toward such costs in an amount
21	equal to not less than \$1 for each \$4 of Federal funds pro-
22	vided in such assistance.''.

1	Subtitle B—National Center for
2	Nursing Research
3	SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR
4	NURSING RESEARCH AS NATIONAL INSTI-
5	TUTE OF NURSING RESEARCH.
6	(a) In General.—Subpart 3 of part E of title IV of
7	the Public Health Service Act (42 U.S.C. 287c et seq.) is
8	amended—
9	(1) in section 483—
10	(A) in the heading for the section, by strik-
11	ing "CENTER" and inserting "INSTITUTE"; and
12	(B) by striking "The general purpose" and
13	all that follows through "is" and inserting the
14	following: "The general purpose of the National
15	Institute of Nursing Research (hereafter in this
16	subpart referred to as the 'Institute') is';
17	(2) in section 484, by striking "Center" each
18	place such term appears and inserting "Institute";
19	(3) in section 485—
20	(A) in subsection (a), in each of paragraphs
21	(1) through (3), by striking "Center" each place
22	such term appears and inserting "Institute";
23	(B) in subsection (b)—
24	(i) in paragraph (2)(A), by striking
25	"Center" and inserting "Institute"; and

1	(ii) in paragraph (3)(A), in the first
2	sentence, by striking "Center" and inserting
3	"Institute"; and
4	(C) in subsections (d) through (g), by strik-
5	ing "Center" each place such term appears and
6	inserting ''Institute''; and
7	(4) in section 485A (as redesignated by section
8	141(a)(1) of this Act), by striking "Center" each place
9	such term appears and inserting "Institute".
10	(b) Conforming Amendments.—
11	(1) Organization of national institutes of
12	HEALTH.—Section 401(b) of the Public Health Serv-
13	ice Act (42 U.S.C. 281(b)) is amended—
14	(A) in paragraph (1), by adding at the end
15	the following new subparagraph:
16	"(Q) The National Institute of Nursing Re-
17	search.''; and
18	(B) in paragraph (2), by striking subpara-
19	graph (D).
20	(2) Transfer of statutory provisions.—The
21	Public Health Service Act, as amended by subsection
22	(a) of this section and by section 124 of Public Law
23	102-321 (106 Stat. 364), is amended—
24	(A) by transferring sections 483 through
25	485A to part C of title IV;

1	(B) by redesignating such sections as sec-
2	tions 464V through 464Y of such part; and
3	(C) by adding such sections, in the appro-
4	priate sequence, at the end of such part.
5	(3) Heading for new subpart.—Title IV of
6	the Public Health Service Act, as amended by the pre-
7	ceding provisions of this section, is amended—
8	(A) in part C, by inserting before section
9	464V the following:
10	"Subpart 17—National Institute of Nursing Research";
11	and
12	(B) by striking the subpart designation and
13	heading for subpart 3 of part E.
14	(4) Cross-references.—Title IV of the Public
15	Health Service Act, as amended by the preceding pro-
16	visions of this section, is amended in subpart 17 of
17	part C—
18	(A) in section 464W, by striking "section
19	483" and inserting "section 464V";
20	(B) in section 464X(g), by striking "section
21	486" and inserting "section 464Y"; and
22	(C) in section 464Y, in the last sentence, by
23	striking ''section 485(g)'' and inserting ''section
24	464X(g) ''.

SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.

2 (a)	IN	GENERAL	-The	Secretary	of	Health	and
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- 3 Human Services, acting through the Director of the Na-
- 4 tional Institute of Nursing Research, shall enter into a con-
- 5 tract with a public or nonprofit private entity to conduct
- 6 a study for the purpose of determining whether and to what
- 7 extent there is a need for an increase in the number of
- 8 nurses in hospitals and nursing homes in order to promote
- 9 the quality of patient care and reduce the incidence among
- 10 nurses of work-related injuries and stress.
- 11 (b) National Academy of Sciences.—The Secretary
- 12 shall request the Institute of Medicine of the National Acad-
- 13 emy of Sciences to enter into the contract under subsection
- 14 (a) to conduct the study described in such subsection. If such
- 15 Institute declines to conduct the study, the Secretary shall
- 16 carry out such subsection through another public or non-
- 17 profit private entity.
- 18 *(c)* Definitions.—For purposes of this section:
- 19 (1) The term "nurse" means a registered nurse,
- 20 a licensed practical nurse, a licensed vocational
- 21 nurse, and a nurse assistant.
- 22 (2) The term "Secretary" means the Secretary of
- 23 Health and Human Services.
- 24 (d) Report.—The Secretary shall ensure that, not
- 25 later than October 1, 1994, the study required in subsection
- 26 (a) is completed and a report describing the findings made

1	as a result of the study is submitted to the Committee on
2	Energy and Commerce of the House of Representatives, and
3	to the Committee on Labor and Human Resources of the
4	Senate.
5	Subtitle C—National Center for
6	Human Genome Research
7	SEC. 1521. PURPOSE OF CENTER.
8	Title IV of the Public Health Service Act, as amended
9	by section 141(a)(1) of this Act and by paragraphs (1)(B)
10	and (3)(B) of section 1511(b) of this Act, is amended—
11	(1) in section $401(b)(2)$, by adding at the end the
12	following new subparagraph:
13	"(D) The National Center for Human Genome
14	Research.''; and
15	(2) in part E, by adding at the end the following
16	new subpart:
17	"Subpart 3—National Center for Human Genome
18	Research
19	"PURPOSE OF THE CENTER
20	"Sec. 485B. (a) The general purpose of the National
21	Center for Human Genome Research (hereafter in this sub-
22	part referred to as the 'Center') is to characterize the struc-
23	ture and function of the human genome, including the map-
24	ping and sequencing of individual genes. Such purpose in-
25	cludes—

1	"(1) planning and coordinating the research goal
2	of the genome project;
3	"(2) reviewing and funding research proposals;
4	"(3) developing training programs;
5	"(4) coordinating international genome research;
6	"(5) communicating advances in genome science
7	to the public; and
8	"(6) reviewing and funding proposals to address
9	the ethical and legal issues associated with the genome
10	project.
11	"(b) The Director of the Center may conduct and sup-
12	port research training—
13	"(1) for which fellowship support is not provided
14	under section 487; and
15	"(2) that is not residency training of physicians
16	or other health professionals.
17	"(c)(1) Except as provided in paragraph (2), of the
18	amounts appropriated to carry out subsection (a) for a fis-
19	cal year, the Director of the Center shall make available
20	not less than 5 percent for carrying out paragraph (6) of
21	such subsection.
22	"(2) With respect to providing funds under subsection
23	(a) (6) for proposals to address the ethical issues associated
24	with the genome project, paragraph (1) shall not apply for
25	a fiscal year if the Director of the Center certifies to the

1	Committee on Energy and Commerce of the House of Rep-
2	resentatives, and to the Committee on Labor and Human
3	Resources of the Senate, that the Director has determined
4	that an insufficient number of such proposals meet the ap-
5	plicable requirements of sections 491 and 492.".
6	TITLE XVI—AWARDS AND
7	TRAINING
8	Subtitle A—National Research
9	Service Awards
10	SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDI-
11	VIDUALS FROM DISADVANTAGED BACK-
12	GROUNDS.
13	Section 487(a) of the Public Health Service Act (42
14	U.S.C. 288(a)(4)) is amended by adding at the end the fol-
15	lowing paragraph:
16	"(4) The Secretary shall carry out paragraph (1) in
17	a manner that will result in the recruitment of women, and
18	individuals from disadvantaged backgrounds, into fields of
19	biomedical or behavioral research and in the provision of
20	research training to women and such individuals.".
21	Subtitle B—Acquired Immune
22	Deficiency Syndrome
23	SEC. 1611. LOAN REPAYMENT PROGRAM.
24	Section 487A of the Public Health Service Act (42
25	U.S.C. 288–1) is amended to read as follows:

1	"LOAN REPAYMENT PROGRAM FOR RESEARCH WITH
2	RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME
3	"Sec. 487A. (a) In General.—
4	"(1) Authority for program.—Subject to
5	paragraph (2), the Secretary shall carry out a pro-
6	gram of entering into agreements with appropriately
7	qualified health professionals under which such health
8	professionals agree to conduct, as employees of the Na-
9	tional Institutes of Health, research with respect to
10	acquired immune deficiency syndrome in consider-
11	ation of the Federal Government agreeing to repay,
12	for each year of such service, not more than \$20,000
13	of the principal and interest of the educational loans
14	of such health professionals.
15	"(2) Limitation.—The Secretary may not enter
16	into an agreement with a health professional pursu-
17	ant to paragraph (1) unless such professional—
18	"(A) has a substantial amount of edu-
19	cational loans relative to income; and
20	"(B) agrees to serve as an employee of the
21	National Institutes of Health for purposes of
22	paragraph (1) for a period of not less than 3
23	years.
24	"(b) Applicability of Certain Provisions.—With
25	respect to the National Health Service Corps Loan Repay-

1	ment Program established in subpart III of part D of title
2	III, the provisions of such subpart shall, except as inconsist-
3	ent with subsection (a) of this section, apply to the program
4	established in such subsection (a) in the same manner and
5	to the same extent as such provisions apply to the National
6	Health Service Corps Loan Repayment Program established
7	in such subpart.
8	"(c) Authorization of Appropriations.—For the
9	purpose of carrying out this section, there are authorized
10	to be appropriated such sums as may be necessary for each
11	of the fiscal years 1994 through 1996.''.
12	Subtitle C—Loan Repayment for
13	Research Generally
14	SEC. 1621. ESTABLISHMENT OF PROGRAM.
14 15	SEC. 1621. ESTABLISHMENT OF PROGRAM. Part G of title IV of the Public Health Service Act,
15	Part G of title IV of the Public Health Service Act,
15 16	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as
15 16 17	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by insert-
15 16 17 18	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section:
15 16 17 18 19	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section: "LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY
115 116 117 118 119 220	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section: "LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY" "Sec. 487C. (a) IN GENERAL.—
115 116 117 118 119 220 221	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section: "LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY "Sec. 487C. (a) IN GENERAL.— "(1) AUTHORITY FOR PROGRAM.—Subject to
15 16 17 18 19 20 21 22	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section: "LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY "Sec. 487C. (a) IN GENERAL.— "(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a pro-
15 16 17 18 19 20 21 22 23	Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section: "LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY "SEC. 487C. (a) IN GENERAL.— "(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately

1	of the Federal Government agreeing to repay, for each
2	year of such service, not more than \$20,000 of the
3	principal and interest of the educational loans of such
4	health professionals.
5	"(2) Limitation.—The Secretary may not enter
6	into an agreement with a health professional pursu-
7	ant to paragraph (1) unless such professional—
8	"(A) has a substantial amount of edu-
9	cational loans relative to income; and
10	"(B) agrees to serve as an employee of the
11	National Institutes of Health for purposes of
12	paragraph (1) for a period of not less than 3
13	years.
14	"(b) Applicability of Certain Provisions.—With
15	respect to the National Health Service Corps Loan Repay-
16	ment Program established in subpart III of part D of title
17	III, the provisions of such subpart shall, except as inconsist-
18	ent with subsection (a) of this section, apply to the program
19	established in such subsection (a) in the same manner and
20	to the same extent as such provisions apply to the National
21	Health Service Corps Loan Repayment Program established
22	in such subpart.
23	"(c) Authorization of Appropriations.—For the
24	purpose of carrying out this section other than with respect
25	to acquired immune deficiency syndrome, there are author-

1	ized to be appropriated such sums as may be necessary for
2	each of the fiscal years 1994 through 1996.''.
3	Subtitle D—Scholarship and Loan
4	Repayment Programs Regarding
5	Professional Skills Needed by
6	Certain Agencies
7	SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL
8	INSTITUTES OF HEALTH.
9	Part G of title IV of the Public Health Service Act,
10	as redesignated by section 141(a)(2) of this Act and as
11	amended by section 1621 of this Act, is amended by insert-
12	ing after section 487C the following new sections:
13	"UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING
14	PROFESSIONS NEEDED BY NATIONAL RESEARCH IN-
15	STITUTES
16	"Sec. 487D. (a) Establishment of Program.—
17	"(1) In GENERAL.—Subject to section
18	487(a)(1)(C), the Secretary, acting through the Direc-
19	tor of NIH, may carry out a program of entering into
20	contracts with individuals described in paragraph (2)
21	under which—
22	"(A) the Director of NIH agrees to provide
23	to the individuals scholarships for pursuing, as
24	undergraduates at accredited institutions of
2.5	higher education academic programs appro-

1	priate for careers in professions needed by the
2	National Institutes of Health; and
3	"(B) the individuals agree to serve as em-
4	ployees of the National Institutes of Health, for
5	the period described in subsection (c), in posi-
6	tions that are needed by the National Institutes
7	of Health and for which the individuals are
8	qualified.
9	"(2) Individuals from disadvantaged back-
10	GROUNDS.—The individuals referred to in paragraph
11	(1) are individuals who—
12	"(A) are enrolled or accepted for enrollment
13	as full-time undergraduates at accredited institu-
14	tions of higher education; and
15	"(B) are from disadvantaged backgrounds.
16	"(b) Facilitation of Interest of Students in Ca-
17	REERS AT NATIONAL INSTITUTES OF HEALTH.—In provid-
18	ing employment to individuals pursuant to contracts under
19	subsection (a)(1), the Director of NIH shall carry out ac-
20	tivities to facilitate the interest of the individuals in pursu-
21	ing careers as employees of the National Institutes of
22	Health.
23	"(c) Period of Obligated Service.—
24	"(1) Duration of Service.—For purposes of
25	subparagraph (B) of subsection (a)(1), the period of

1	service for which an individual is obligated to serve
2	as an employee of the National Institutes of Health
3	is, subject to paragraph (2)(A), 12 months for each
4	academic year for which the scholarship under such
5	subsection is provided.
6	"(2) Schedule for service.—
7	"(A) Subject to subparagraph (B), the Di-
8	rector of NIH may not provide a scholarship
9	under subsection (a) unless the individual apply-
10	ing for the scholarship agrees that—
11	"(i) the individual will serve as an em-
12	ployee of the National Institutes of Health
13	full-time for not less than 10 consecutive
14	weeks of each year during which the indi-
15	vidual is attending the educational institu-
16	tion involved and receiving such a scholar-
17	ship;
18	"(ii) the period of service as such an
19	employee that the individual is obligated to
20	provide under clause (i) is in addition to
21	the period of service as such an employee
22	that the individual is obligated to provide
23	under subsection (a)(1)(B); and
24	"(iii) not later than 60 days after ob-
25	taining the educational degree involved, the

1	individual will begin serving full-time as
2	such an employee in satisfaction of the pe-
3	riod of service that the individual is obli-
4	gated to provide under subsection (a)(1)(B).
5	"(B) The Director of NIH may defer the ob-
6	ligation of an individual to provide a period of
7	service under subsection (a)(1)(B), if the Direc-
8	tor determines that such a deferral is appro-
9	priate.
10	"(3) Applicability of certain provisions re-
11	LATING TO APPOINTMENT AND COMPENSATION.—For
12	any period in which an individual provides service as
13	an employee of the National Institutes of Health in
14	satisfaction of the obligation of the individual under
15	subsection (a)(1)(B) or paragraph (2)(A)(i), the indi-
16	vidual may be appointed as such an employee with-
17	out regard to the provisions of title 5, United States
18	Code, relating to appointment and compensation.
19	"(d) Provisions Regarding Scholarship.—
20	"(1) Approval of academic program.—The
21	Director of NIH may not provide a scholarship under
22	subsection (a) for an academic year unless—
23	"(A) the individual applying for the schol-
24	arship has submitted to the Director a proposed

1	academic program for the year and the Director
2	has approved the program; and
3	"(B) the individual agrees that the program
4	will not be altered without the approval of the
5	Director.
6	"(2) Academic standing.—The Director of
7	NIH may not provide a scholarship under subsection
8	(a) for an academic year unless the individual apply-
9	ing for the scholarship agrees to maintain an accept-
10	able level of academic standing, as determined by the
11	educational institution involved in accordance with
12	regulations issued by the Secretary.
13	"(3) Limitation on amount.—The Director of
14	NIH may not provide a scholarship under subsection
15	(a) for an academic year in an amount exceeding
16	\$20,000.
17	"(4) AUTHORIZED USES.—A scholarship pro-
18	vided under subsection (a) may be expended only for
19	tuition expenses, other reasonable educational ex-
20	penses, and reasonable living expenses incurred in at-
21	tending the school involved.
22	"(5) Contract regarding direct payments
23	TO INSTITUTION.—In the case of an institution of
24	higher education with respect to which a scholarship
25	under subsection (a) is provided the Director of NIH

- 1 may enter into a contract with the institution under
- 2 which the amounts provided in the scholarship for
- 3 tuition and other educational expenses are paid di-
- 4 rectly to the institution.
- 5 "(e) Penalties for Breach of Scholarship Con-
- 6 TRACT.—The provisions of section 338E shall apply to the
- 7 program established in subsection (a) to the same extent
- 8 and in the same manner as such provisions apply to the
- 9 National Health Service Corps Loan Repayment Program
- 10 established in section 338B.
- 11 "(f) REQUIREMENT OF APPLICATION.—The Director of
- 12 NIH may not provide a scholarship under subsection (a)
- 13 unless an application for the scholarship is submitted to
- 14 the Director and the application is in such form, is made
- 15 in such manner, and contains such agreements, assurances,
- 16 and information as the Director determines to be necessary
- 17 to carry out this section.
- 18 "(g) Availability of Authorization of Appro-
- 19 PRIATIONS.—Amounts appropriated for a fiscal year for
- 20 scholarships under this section shall remain available until
- 21 the expiration of the second fiscal year beginning after the
- 22 fiscal year for which the amounts were appropriated.
- 23 "LOAN REPAYMENT PROGRAM REGARDING CLINICAL
- 24 RESEARCHERS FROM DISADVANTAGED BACKGROUNDS
- 25 "Sec. 487E. (a) Implementation of Program.—

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"(1) INGENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than \$20,000 of the principal and interest of the educational loans of the health professionals.

- "(2) Limitation.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.
- "(3) APPLICABILITY OF CERTAIN PROVISIONS RE-GARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

1	"(b) Availability of Authorization of Appro-
2	PRIATIONS.—Amounts appropriated for a fiscal year for
3	contracts under subsection (a) shall remain available until
4	the expiration of the second fiscal year beginning after the
5	fiscal year for which the amounts were appropriated.".
6	SEC. 1632. FUNDING.
7	Section 487(a)(1) of the Public Health Service Act (42
8	U.S.C. 288(a)(1)) is amended—
9	(1) in subparagraph (A), by striking "and" after
10	the semicolon at the end;
11	(2) in subparagraph (B), by striking the period
12	at the end and inserting "; and"; and
13	(3) by inserting after subparagraph (B) the fol-
14	lowing new subparagraph:
15	"(C) provide contracts for scholarships and loan
16	repayments in accordance with sections 487D and
17	487E, subject to providing not more than an aggre-
18	gate 50 such contracts during the fiscal years 1994
19	through 1996.''.
20	Subtitle E—Funding
21	SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.
22	Section 487(d) of the Public Health Service Act (42
23	U.S.C. 288(d)) is amended—
24	(1) in the first sentence, by amending the sen-
25	tence to read as follows: "For the nurnose of carrying

1	out this section, there are authorized to be appro-
2	priated \$400,000,000 for fiscal year 1994, and such
3	sums as may be necessary for each of the fiscal years
4	1995 and 1996.''; and
5	(2) in paragraph (3)—
6	(A) by striking "one-half of one percent"
7	each place such term appears and inserting "1
8	percent"; and
9	(B) by striking "780, 784, or 786," and in-
10	serting ''747, 748, or 749,''.
11	TITLE XVII—NATIONAL FOUNDA-
	TION FOR BIOMERICAL DE
12	TION FOR BIOMEDICAL RE-
12 13	SEARCH
13	SEARCH
13 14	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD
13 14 15 16	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS.
13 14 15 16	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS. Section 499 of the Public Health Service Act, as redes-
13 14 15 16	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS. Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended in sub-
113 114 115 116 117	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS. Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended in subsection (c)(1)(C) by inserting after and below clause (iii)
13 14 15 16 17 18	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS. Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended in subsection (c)(1)(C) by inserting after and below clause (iii) the following:
13 14 15 16 17 18 19 20	SEARCH SEC. 1701. DATE CERTAIN FOR APPOINTMENT OF BOARD MEMBERS. Section 499 of the Public Health Service Act, as redesignated by section 121(b)(3) of this Act, is amended in subsection (c)(1)(C) by inserting after and below clause (iii) the following: "Not later than April 1, 1993, the Secretary

1 SEC. 1702. MISCELLANEOUS PROVISIONS.

2	Section 499 of the Public Health Service Act, as redes-
3	ignated by section 121(b)(3) of this Act, is amended—
4	(1) in subsection (a)—
5	(A) in the first sentence, by inserting after
6	"Secretary" the following: ", acting through the
7	Director of NIH, "; and
8	(B) in the second sentence, by striking "the
9	purposes of" and all that follows through
10	"Transfer Act," and inserting the following: "the
11	purposes of the Ethics in Government Act of
12	1978 and the Stevenson-Wydler Technology In-
13	novation Act of 1980, ";
14	(2) in subsection (b)(2), by striking "Ethics"
15	and all that follows and inserting the following: "Eth-
16	ics in Government Act of 1978, and the Stevenson-
17	Wydler Technology Innovation Act of 1980.";
18	(3) in subsection (c)—
19	(A) in paragraph (1)—
20	(i) in subparagraph (A), in the second
21	sentence, by inserting ", except the ex officio
22	members, " after "Foundation";
23	(ii) in subparagraph (B), in the mat-
24	ter preceding clause (i), by striking "Coun-
25	cil'' and inserting "Board"; and

1	(iii) in subparagraph (C), in the first
2	sentence, by striking "Council" and insert-
3	ing "Board"; and
4	(B) in paragraph (3)(A), by striking "para-
5	graph (2)(C)'' and inserting ''paragraph
6	(1)(C)'';
7	(4) in subsection (g)(8), by striking ''subtitle''
8	and inserting ''part''; and
9	(5) in subsection (i)(1), by striking "1995" and
10	inserting ''1996''.
11	TITLE XVIII—RESEARCH WITH
12	RESPECT TO ACQUIRED IM-
13	MUNE DEFICIENCY SYN-
14	DROME
15	Subtitle A—Office of AIDS Research
16	SEC. 1801. ESTABLISHMENT OF OFFICE.
17	(a) In General.—Part D of title XXIII of the Public
18	Health Service Act (42 U.S.C. 300cc-41 et seq.) is amend-
19	ed—
20	(1) by striking the part designation and the
21	heading for the part;
22	(2) by redesignating section 2351 as section
23	2354; and
24	(3) by inserting before section 2354 (as so redes-
25	ignated) the following:

1	PART D—OFFICE OF AIDS RESEARCH
2	"Subpart I—Interagency Coordination of Activities
3	"SEC. 2351. ESTABLISHMENT OF OFFICE.
4	"(a) In General.—There is established within the
5	National Institutes of Health an office to be known as the
6	Office of AIDS Research. The Office shall be headed by a
7	director, who shall be appointed by the Secretary.
8	"(b) Duties.—
9	"(1) Interagency coordination of aids ac-
10	TIVITIES.—With respect to acquired immune defi-
11	ciency syndrome, the Director of the Office shall plan,
12	coordinate, and evaluate research and other activities
13	conducted or supported by the agencies of the Na-
14	tional Institutes of Health.
15	"(2) Consultations.—The Director of the Of-
16	fice shall carry out this subpart (including developing
17	and revising the plan required in section 2353) in
18	consultation with the heads of the agencies of the Na-
19	tional Institutes of Health, with the advisory councils
20	of the agencies, and with the advisory council estab-
21	lished under section 2352.
22	"SEC. 2352. ADVISORY COUNCIL.
23	"(a) In General.—The Secretary shall establish an
24	advisory council for the purpose of providing advice to the

1	Director of the Office on carrying out this part. (Such coun-
2	cil is referred to in this section as the 'Advisory Council'.)
3	"(b) Composition, Compensation, Terms, Chair,
4	ETC.—Subsections (b) through (g) of section 406 apply to
5	the Advisory Council to the same extent and in the same
6	manner as such subsections apply to advisory councils for
7	the national research institutes, except that, in addition to
8	the ex officio members specified in section 406(b)(2), there
9	shall serve as ex officio members of the Advisory Council
10	the chairs of the advisory councils for each of the National
11	Cancer Institute, the National Institute on Allergy and In-
12	fectious Diseases, the National Institute on Drug Abuse, and
13	the National Institute on Mental Health.
14	"SEC. 2353. COMPREHENSIVE PLAN FOR EXPENDITURE OF
15	APPROPRIATIONS.
16	"(a) In General.—Subject to the provisions of this
17	"(a) In General.—Subject to the provisions of this
17	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office,
17 18	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall—
17 18 19	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall— "(1) establish a comprehensive plan for the con-
17 18 19 20	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall— "(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agen-
17 18 19 20 21	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall— "(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan
17 18 19 20 21 22	"(a) In General.—Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 2351, shall— "(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plans shall be first established under this paragraph not

1	"(2) ensure that the Plan establishes priorities
2	among the AIDS activities that such agencies are au-
3	thorized to carry out;
4	"(3) ensure that the Plan establishes objectives
5	regarding such activities, describes the means for
6	achieving the objectives, and designates the date by
7	which the objectives are expected to be achieved;
8	"(4) ensure that all amounts appropriated for
9	such activities are expended in accordance with the
10	Plan;
11	"(5) review the Plan not less than annually, and
12	revise the Plan as appropriate; and
13	"(6) ensure that the Plan serves as a broad,
14	binding statement of policies regarding AIDS activi-
15	ties of the agencies, but does not remove the respon-
16	sibility of the heads of the agencies for the approval
17	of specific programs or projects, or for other details of
18	the daily administration of such activities, in accord-
19	ance with the Plan.
20	"(b) Certain Components of Plan.—With respect
21	to AIDS activities of the agencies of the National Institutes
22	of Health, the Director of the Office shall ensure that the
23	Plan—
24	"(1) provides for basic research;
25	"(2) provides for applied research;

1	"(3) provides for research that is conducted by
2	the agencies;
3	"(4) provides for research that is supported by
4	the agencies;
5	"(5) provides for proposals developed pursuant to
6	solicitations by the agencies and for proposals devel-
7	oped independently of such solicitations; and
8	"(6) provides for behavioral research and social
9	sciences research.
10	"(c) Budget Estimates.—
11	"(1) Full-funding budget.—
12	"(A) With respect to a fiscal year, the Di-
13	rector of the Office shall prepare and submit di-
14	rectly to the President, for review and transmit-
15	tal to the Congress, a budget estimate for carry-
16	ing out the Plan for the fiscal year, after reason-
17	able opportunity for comment (but without
18	change) by the Secretary, the Director of the Na-
19	tional Institutes of Health, and the advisory
20	council established under section 2352. The budg-
21	et estimate shall include an estimate of the num-
22	ber and type of personnel needs for the Office.
23	"(B) The budget estimate submitted under
24	subparagraph (A) shall estimate the amounts
25	necessary for the agencies of the National Insti-

1	tutes of Health to carry out all AIDS activities
2	determined by the Director of the Office to be ap-
3	propriate, without regard to the probability that
4	such amounts will be appropriated.
5	"(2) Alternative budgets.—
6	"(A) With respect to a fiscal year, the Di-
7	rector of the Office shall prepare and submit to
8	the Secretary and the Director of the National
9	Institutes of Health the budget estimates de-
10	scribed in subparagraph (B) for carrying out the
11	Plan for the fiscal year. The Secretary and such
12	Director shall consider each of such estimates in
13	making recommendations to the President re-
14	garding a budget for the Plan for such year.
15	"(B) With respect to the fiscal year in-
16	volved, the budget estimates referred to in sub-
17	paragraph (A) for the Plan are as follows:
18	"(i) The budget estimate submitted
19	under paragraph (1).
20	"(ii) A budget estimate developed on
21	the assumption that the amounts appro-
22	priated will be sufficient only for—
23	"(I) continuing the conduct by the
24	agencies of the National Institutes of
25	Health of existing AIDS activities (if

1	approved for continuation), and con-
2	tinuing the support of such activities
3	by the agencies in the case of projects
4	or programs for which the agencies
5	have made a commitment of continued
6	support; and
7	"(II) carrying out, of activities
8	that are in addition to activities speci-
9	fied in subclause (I), only such activi-
10	ties for which the Director determines
11	there is the most substantial need.
12	"(iii) Such other budget estimates as
13	the Director of the Office determines to be
14	appropriate.
15	"(d) Funding.—
16	"(1) Authorization of appropriations.—For
17	the purpose of carrying out AIDS activities under the
18	Plan, there are authorized to be appropriated such
19	sums as may be necessary for each of the fiscal years
20	1994 through 1996.
21	"(2) Direct receipt by director of NA-
22	TIONAL INSTITUTES OF HEALTH.—For the first fiscal
23	year beginning after the date on which the Plan first
24	established under section 2353(a)(1) has been in effect
25	for 12 months, and for each subsequent fiscal year, the

Director of the National Institutes of Health shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

"(3) Disbursement to Agencies.—

"(A) With respect to the disbursement by the Director of the National Institutes of Health of amounts for carrying out AIDS activities specified in subsection (c)(2)(B)(ii)(I) for the fiscal year involved, the Director shall, to the extent practicable, disburse all of such amounts to the agencies of such Institutes not later than 30 days after the date on which the Director receives amounts under paragraph (2).

"(B) With respect to the disbursement by the Director of the National Institutes of Health of amounts for carrying out AIDS activities of the National Institutes of Health in addition to the activities specified in subparagraph (A) for the fiscal year, the Director shall, to the extent practicable, disburse all of such amounts to the agencies of the National Institutes of Health not later than 90 days after the date on which the

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1	Director receives amounts under paragraph
2	(2). ''.
3	(b) Conforming Amendments.—Section 2354 of the
4	Public Health Service Act, as redesignated by subsection
5	(a) (2) of this section, is amended—
6	(1) in the heading for the section, by striking
7	"ESTABLISHMENT OF" and inserting "ADDI-
8	TIONAL'';
9	(2) in subsection (a)—
10	(A) in the matter preceding paragraph (1),
11	by striking "In carrying out" and all that fol-
12	lows and inserting the following: "In carrying
13	out AIDS research, the Director of the Of-
14	fice—'';
15	(B) by striking paragraphs (1) and (2) and
16	redesignating paragraphs (3) through (8) as
17	paragraphs (1) through (6);
18	(C) in paragraph (3) (as so redesignated),
19	by striking "may" and all that follows in the
20	matter preceding subparagraph (A) and insert-
21	ing the following: "may support";
22	(D) in paragraph (5) (as so redesignated)—
23	(i) in subparagraph (A)—

1	"(I) by striking "may" and all
2	that follows through ''acquire,'' and in-
3	serting "may acquire,"; and
4	"(II) by striking "Director" and
5	all that follows through ''determines''
6	and inserting "Director of the Office
7	determines'';
8	(ii) in subparagraph (B), by striking
9	"may" and all that follows through "make
10	grants'' and inserting 'may make grants'';
11	and
12	(iii) in subparagraph (C), by striking
13	"may" and all that follows through "ac-
14	quire,'' and inserting 'may acquire,''; and
15	(E) in each of paragraphs (2), (3)(A), and
16	(4) (as so redesignated), by striking "research re-
17	lating to acquired immune deficiency syndrome"
18	and inserting "AIDS research";
19	(3) in subsection (b), in the matter preceding
20	paragraph (1), by striking "The Director" and all
21	that follows through ''shall'' and inserting ''The Di-
22	rector of the Office shall"; and
23	(4) in subsection (c), by striking "the Director"
24	and all that follows through "shall" and inserting
25	"the Director of the Office shall".

1	SEC. 1802. ESTABLISHMENT OF EMERGENCY DISCRE-
2	TIONARY FUND.
3	Part D of title XXIII of the Public Health Service Act,
4	as amended by section 1801 of this Act, is amended by add-
5	ing at the end the following subpart:
6	"Subpart II—Emergency Discretionary Fund
7	"SEC. 2356. EMERGENCY DISCRETIONARY FUND.
8	"(a) In General.—
9	"(1) Establishment.—There is established a
0	fund consisting of such amounts as may be appro-
1	priated under subsection (g). Subject to the provisions
2	of this section, the Director of the Office, after con-
3	sultation with the advisory council established under
4	section 2352, may expend amounts in the Fund for
5	the purpose of conducting and supporting such
6	projects of AIDS research and other AIDS activities
7	as may be authorized in this Act for the National In-
8	stitutes Health.
9	"(2) Preconditions to use of fund.—
20	Amounts in the Fund may be expended for an AIDS
21	project only if—
22	"(A) the Director of the Office has made a
23	determination that there is a significant need for
24	the project; and
25	"(B) as of June 30 of the fiscal year preced-
26	ing the fiscal year in which the determination is

1	made, such need was not provided for in any ap-
2	propriations Act passed by the House of Rep-
3	resentatives to make appropriations for the De-
4	partments of Labor, Health and Human Services
5	(including the National Institutes of Health),
6	Education, and related agencies for the fiscal
7	year in which the determination is made.
8	"(3) Two-year use of fund for project in-
9	VOLVED.—In the case of an AIDS project, obligations
10	of amounts in the Fund may not be made for the
11	project after the expiration of the 2-year period begin-
12	ning on the date on which the initial obligation of
13	such amounts is made for the project.
14	"(b) PEER REVIEW.—With respect to an AIDS project
15	carried out with amounts in the Fund, this section may
16	not be construed as waiving applicable requirements for
17	peer review.
18	"(c) Limitations on Use of Fund.—
19	"(1) Construction of facilities.—Amounts
20	in the Fund may not be used for the construction,
21	renovation, or relocation of facilities, or for the acqui-
22	sition of land.
23	"(2) Congressional disapproval of
24	PRO IECTS —

1	"(A) Amounts in the Fund may not be ex-
2	pended for the fiscal year involved for an AIDS
3	project, or category of such projects, for which—
4	``(i)(I) amounts were made available
5	in an appropriations Act for the preceding
6	fiscal year; and
7	"(II) amounts are not made available
8	in any appropriations Act for the fiscal
9	year involved; or
10	"(ii) amounts are by law prohibited
11	from being expended.
12	"(B) A determination under subparagraph
13	(A)(i) of whether amounts have been made avail-
14	able in appropriations Acts for a fiscal year
15	shall be made without regard to whether such
16	Acts make available amounts for the Fund.
17	"(3) Investment of fund amounts.—Amounts
18	in the Fund may not be invested.
19	"(d) Applicability of Limitation Regarding Num-
20	BER OF Employees.—The purposes for which amounts in
21	the Fund may be expended include the employment of indi-
22	viduals necessary to carry out AIDS projects approved
23	under subsection (a). Any individual employed under the
24	preceding sentence may not be included in any determina-
25	tion of the number of full-time equivalent employees for the

1	Department of Health and Human Services for the purpose
2	of any limitation on the number of such employees estab-
3	lished by law prior to, on, or after the date of the enactment
4	of the National Institutes of Health Revitalization Act of
5	1993.
6	"(e) Report to Congress.—Not later than February
7	1 of each fiscal year, the Director of the Office shall submit
8	to the Committee on Energy and Commerce of the House
9	of Representatives, and to the Committee on Labor and
10	Human Resources of the Senate, a report on the AIDS
11	projects carried out during the preceding fiscal year with
12	amounts in the Fund. The report shall provide a descrip-
13	tion of each such project and an explanation of the reasons
14	underlying the use of the Fund for the project.
15	"(f) Definitions.—For purposes of this section:
16	''(1) The term 'AIDS project' means a project de-
17	scribed in subsection (a).
18	"(2) The term 'Fund' means the fund established
19	in subsection (a).
20	"(g) Funding.—
21	"(1) Authorization of appropriations.—For
22	the purpose of providing amounts for the Fund, there
23	is authorized to be appropriated \$100,000,000 for
24	each of the fiscal years 1994 through 1996.

1	"(2) AVAILABILITY.—Amounts appropriated for
2	the Fund are available until expended.".
3	SEC. 1803. GENERAL PROVISIONS.
4	Part D of title XXIII of the Public Health Service Act,
5	as amended by section 1802 of this Act, is amended by add-
6	ing at the end the following subpart:
7	"Subpart III—General Provisions
8	"SEC. 2359. GENERAL PROVISIONS REGARDING THE OF
9	FICE.
10	"(a) Administrative Support for Office.—The
11	Secretary, acting through the Director of the National Insti-
12	tutes of Health, shall provide administrative support and
13	support services to the Director of the Office.
14	"(b) Definitions.—For purposes of this part:
15	"(1) The term 'AIDS activities' means AIDS re-
16	search and other activities that relate to acquired im-
17	mune deficiency syndrome.
18	"(2) The term 'AIDS research' means research
19	with respect to acquired immune deficiency syndrome.
20	"(3) The term 'Office' means the Office of AIDS
21	Research.
22	"(4) The term 'Plan' means the plan required in
23	section 2353(a)(1) ''

Subtitle B—Certain Programs 1 SEC. 1811. REVISION AND EXTENSION OF CERTAIN PRO-3 GRAMS. Title XXIII of the Public Health Service Act (42) 4 U.S.C. 300cc et seq.) is amended— 5 6 (1) in section 2304(c)(1)— (A) in the matter preceding subparagraph 7 (A), by inserting after "Director of such Insti-8 tute" the following: "(and may provide advice to 9 the Directors of other agencies of the National 10 Institutes of Health, as appropriate)"; and 11 12 (B) in subparagraph (A), by inserting before the semicolon the following: ", including rec-13 ommendations on the projects of research with 14 respect to diagnosing immune deficiency and 15 with respect to predicting, diagnosing, prevent-16 17 ing, and treating opportunistic cancers and infectious diseases": 18 19 (2) in section 2311(a)(1), by inserting before the semicolon the following: ", including evaluations of 20 21 methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, 22 and treating opportunistic cancers and infectious 23 24 diseases": (3) in section 2315—

1	(A) in subsection (a)(2), by striking "inter-
2	national research" and all that follows and in-
3	serting ''international research and training
4	concerning the natural history and pathogenesis
5	of the human immunodeficiency virus and the
6	development and evaluation of vaccines and
7	treatments for acquired immune deficiency syn-
8	drome and opportunistic infections."; and
9	(B) in subsection (f), by striking ''there are
10	authorized" and all that follows and inserting
11	"there are authorized to be appropriated such
12	sums as may be necessary for each fiscal year.';
13	(4) in section 2318—
14	(A) in subsection (a)(1)—
15	(i) by inserting after "The Secretary"
16	the following: ", acting through the Director
17	of the National Institutes of Health and
18	after consultation with the Administrator
19	for Health Care Policy and Research,''; and
20	(ii) by striking "syndrome" and insert-
21	ing ''syndrome, including treatment and
22	prevention of HIV infection and related
23	conditions among women''; and
24	(B) in subsection (e), by striking "1991."
25	and inserting the following: "1991, and such

1	sums as may be necessary for each of the fiscal
2	years 1994 through 1996.'';
3	(5) in section 2320(b)(1)(A), by striking "syn-
4	drome" and inserting "syndrome and the natural his-
5	tory of such infection";
6	(6) in section 2320(e)(1), by striking "there are
7	authorized" and all that follows and inserting "there
8	are authorized to be appropriated such sums as may
9	be necessary for each fiscal year.";
10	(7) in section 2341(d), by striking "there are au-
11	thorized" and all that follows and inserting "there are
12	authorized to be appropriated such sums as may be
13	necessary for each fiscal year.''; and
14	(8) in section 2361, by striking "For purposes"
15	and all that follows and inserting the following:
16	"For purposes of this title:
17	"(1) The term 'infection', with respect to the etio-
18	logic agent for acquired immune deficiency syndrome,
19	includes opportunistic cancers and infectious diseases
20	and any other conditions arising from infection with
21	such etiologic agent.
22	"(2) The term 'treatment', with respect to the
23	etiologic agent for acquired immune deficiency syn-
24	drome, includes primary and secondary prophy-
25	laxis.''.

1 TITLE XIX—STUDIES

2	SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.
3	(a) Third-Party Payments Regarding Certain
4	CLINICAL TRIALS.—The Secretary of Health and Human
5	Services, acting through the Director of the National Insti-
6	tutes of Health, shall conduct a study for the purpose of—
7	(1) determining the policies of third-party
8	payors regarding the payment of the costs of appro-
9	priate health services that are provided incident to
10	the participation of individuals as subjects in clinical
11	trials conducted in the development of drugs with re-
12	spect to acquired immune deficiency syndrome; and
13	(2) developing recommendations regarding such
14	policies.
15	(b) Advisory Committees.—The Secretary of Health
16	and Human Services, acting through the Director of the Na-
17	tional Institutes of Health, shall conduct a study for the
18	purpose of determining—
19	(1) whether the activities of the various advisory
20	committees established in the National Institutes of
21	Health regarding acquired immune deficiency syn-
22	drome are being coordinated sufficiently; and
23	(2) whether the functions of any of such advisory
24	committees should be modified in order to achieve
25	greater efficiency.

1	(c) Vaccines for Human Immunodeficiency
2	Virus.—
3	(1) In general.—The Secretary of Health and
4	Human Services, acting through the National Insti-
5	tutes of Health, shall develop a plan for the appro-
6	priate inclusion of HIV-infected women, including
7	pregnant women, HIV-infected infants, and HIV-in-
8	fected children in studies conducted by or through the
9	National Institutes of Health concerning the safety
10	and efficacy of HIV vaccines for the treatment and
11	prevention of HIV infection. Such plan shall ensure
12	the full participation of other Federal agencies cur-
13	rently conducting HIV vaccine studies and require
14	that such studies conform fully to the requirements of
15	part 46 of title 45, Code of Federal Regulations.
16	(2) Report.—Not later than 180 days after the
17	date of the enactment of this Act, the Secretary of
18	Health and Human Services shall prepare and sub-
19	mit to the Committee on Energy and Commerce of the
20	House of Representatives, and the Committee on
21	Labor and Human Resources of the Senate, a report
22	concerning the plan developed under paragraph (1).
23	(3) Implementation.—Not later than 12
24	months after the date of the enactment of this Act, the
25	Secretary of Health and Human Services shall imple-

ment the plan developed under paragraph (1), includ ing measures for the full participation of other
 Federal agencies currently conducting HIV vaccine
 studies.

(4) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

9 SEC. 1902. MALNUTRITION IN THE ELDERLY.

10 (a) STUDY.—

- (1) In General.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the National Institute on Aging, coordinating with the Agency for Health Care Policy and Research and, to the degree possible, in consultation with the head of the National Nutrition Monitoring System established under section 1428 of the Food and Agriculture Act of 1977 (7 U.S.C. 3178), shall conduct a 3-year nutrition screening and intervention activities study of the elderly.
- (2) Efficacy and cost-effectiveness of nutrition screening and intervention activities of nutrition screening and intervention activities conducted

1	in the elderly health and long-term care continuum,
2	and of a program that would institutionalize nutri-
3	tion screening and intervention activities. In evaluat-
4	ing such a program, the Secretary shall determine—
5	(A) if health or quality of life is measurably
6	improved for elderly individuals who receive rou-
7	tine nutritional screening and treatment;
8	(B) if federally subsidized home or institu-
9	tional care is reduced because of increased inde-
10	pendence of elderly individuals resulting from
11	improved nutritional status;
12	(C) if a multidisciplinary approach to nu-
13	tritional care is effective in addressing the nutri-
14	tional needs of elderly individuals; and
15	(D) if reimbursement for nutrition screen-
16	ing and intervention activities is a cost-effective
17	approach to improving the health status of elder-
18	ly individuals.
19	(3) POPULATIONS.—The populations of elderly
20	individuals in which the study will be conducted shall
21	include populations of elderly individuals who are—
22	(A) living independently, including—
23	(i) individuals who receive home and
24	community-based services or family sup-
25	port;

1	(ii) individuals who do not receive ad-
2	ditional services and support;
3	(iii) individuals with low incomes; and
4	(iv) individuals who are minorities;
5	(B) hospitalized, including individuals ad-
6	mitted from home and from institutions; and
7	(C) institutionalized in residential facilities
8	such as nursing homes and adult homes.
9	(b) Malnutrition Study.—The Secretary, acting
10	through the National Institute on Aging, shall conduct a
11	3-year study to determine the extent of malnutrition in el-
12	derly individuals in hospitals and long-term care facilities
13	and in elderly individuals who are living independently.
14	(c) Report.—The Secretary shall submit a report to
15	the Committee on Labor and Human Resources of the Sen-
16	ate and the Committee on Energy and Commerce of the
17	House of Representatives containing the findings resulting
18	from the studies described in subsections (a) and (b), in-
19	cluding a determination regarding whether a program that
20	would institutionalize nutrition screening and intervention
21	activities should be adopted, and the rationale for the deter-
22	mination.
23	(d) Advisory Panel.—
24	(1) Establishment.—The Secretary, acting
25	through the Director of the National Institute on

1 Aging, shall establish an advisory panel that shall 2 oversee the design, implementation, and evaluation of 3 the studies described in subsections (a) and (b).

(2) Composition.—The advisory panel shall include representatives appointed for the life of the panel by the Secretary from the Health Care Financing Administration, the Social Security Administration, the National Center for Health Statistics, the Administration on Aging, the National Council on the Aging, the American Dietetic Association, the American Academy of Family Physicians, and such other agencies or organizations as the Secretary determines to be appropriate.

(3) Compensation and expenses.—

(A) Compensation.—Each member of the advisory panel who is not an employee of the Federal Government shall receive compensation at the daily equivalent of the rate specified for level V of the Executive Schedule under section 5316 of title 5, United States Code, for each day the member is engaged in the performance of duties for the advisory panel, including attendance at meetings and conferences of the panel, and travel to conduct the duties of the panel.

- (B) Travel expenses.—Each member of the advisory panel shall receive travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, for each day the member is engaged in the performance of duties away from the home or regular place of business of the member.
 - (4) Detail of Federal employees.—On the request of the advisory panel, the head of any Federal agency shall detail, without reimbursement, any of the personnel of the agency to the advisory panel to assist the advisory panel in carrying out its duties. Any detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.
 - (5) TECHNICAL ASSISTANCE.—On the request of the advisory panel, the head of a Federal agency shall provide such technical assistance to the advisory panel as the advisory panel determines to be necessary to carry out its duties.
 - (6) Termination.—Notwithstanding section 15 of the Federal Advisory Committee Act (5 U.S.C. App.), the advisory panel shall terminate 3 years after the date of enactment of this Act.

1	SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE
2	SYNDROME.
3	The Secretary of Health and Human Services shall,
4	not later than May 1, 1993, and annually thereafter for
5	the next 3 years, prepare and submit to the Committee on
6	Energy and Commerce of the House of Representatives and
7	the Committee on Labor and Human Resources of the Sen-
8	ate, a report that summarizes the research activities con-
9	ducted or supported by the National Institutes of Health
10	concerning chronic fatigue syndrome. Such report should
11	include information concerning grants made, cooperative
12	agreements or contracts entered into, intramural activities,
13	research priorities and needs, and a plan to address such
14	priorities and needs.
15	SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL
16	AGENTS IN DEVELOPMENT OF DEFENSES
17	AGAINST BIOLOGICAL WARFARE.
18	The Secretary of Health and Human Services, in con-
19	sultation with other appropriate executive agencies, shall
20	report to the House Energy and Commerce Committee and
21	the Senate Labor and Human Resources Committee on the
22	appropriateness and impact of the National Institutes of
23	Health assuming responsibility for the conduct of all Fed-
24	eral research, development, testing, and evaluation func-
25	tions relating to medical countermeasures against
26	biowarfare threat agents. In preparing the report, the Sec-

- 1 retary shall identify the extent to which such activities are
- 2 carried out by agencies other than the National Institutes
- 3 of Health, and assess the impact (positive and negative) of
- 4 the National Institutes of Health assuming responsibility
- 5 for such activities, including the impact under the Budget
- 6 Enforcement Act and the Omnibus Budget Reconciliation
- 7 Act of 1990 on existing National Institutes of Health re-
- 8 search programs as well as other programs within the cat-
- 9 egory of domestic discretionary spending. The Secretary
- 10 shall submit the report not later than 12 months after the
- 11 date of the enactment of this Act.
- 12 SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETEN-
- 13 **TION AND TURNOVER.**
- 14 (a) Study of Personnel System.—Not later than
- 15 1 year after the date of the enactment of this Act, the Sec-
- 16 retary of Health and Human Services, acting through the
- 17 Director of the National Institutes of Health, shall conduct
- 18 a study to review the retention, recruitment, vacancy and
- 19 turnover rates of support staff, including firefighters, law
- 20 enforcement, procurement officers, technicians, nurses and
- 21 clerical employees, to ensure that the National Institutes of
- 22 Health is adequately supporting the conduct of efficient, ef-
- 23 fective and high quality research for the American public.
- 24 The Director of NIH shall work in conjunction with appro-

- 1 priate employee organizations and representatives in devel-
- 2 oping such a study.
- 3 (b) Submission to Congress.—Not later than 1 year
- 4 after the date of the enactment of this Act, the Secretary
- 5 of Health and Human Services shall prepare and submit
- 6 to the Committee on Energy and Commerce of the House
- 7 of Representatives, and to the Committee on Labor and
- 8 Human Resources of the Senate, a report containing the
- 9 study conducted under subsection (a) together with the rec-
- 10 ommendations of the Secretary concerning the enactment
- 11 of legislation to implement the results of such study.

12 **SEC. 1906. PROCUREMENT.**

- 13 (a) In General.—The Director of the National Insti-
- 14 tutes of Health and the Administrator of the General Serv-
- 15 ices Administration shall jointly conduct a study to develop
- 16 a streamlined procurement system for the National Insti-
- 17 tutes of Health that complies with the requirements of Fed-
- 18 eral law.
- 19 (b) REPORT.—Not later than March 1, 1994, the offi-
- 20 cials specified in subsection (a) shall complete the study re-
- 21 quired in such subsection and shall submit to the Committee
- 22 on Energy and Commerce of the House of Representatives,
- 23 and the Committee on Labor and Human Resources of the
- 24 Senate, a report describing the findings made as a result
- 25 of the study.

SEC. 1907. CHRONIC PAIN CONDITIONS.

- 2 (a) In General.—The Director of the National Insti-
- 3 tutes of Health (in this section referred to as the 'Director'),
- 4 acting through the Director of the National Institute of Den-
- 5 tal Research and as appropriate through the heads of other
- 6 agenices of such Institutes, shall conduct a study for the
- 7 purpose of determining the incidence in the United States
- 8 of cases of chronic pain and the effect of such cases on the
- 9 costs of health care in the United States.
- 10 (b) CERTAIN ELEMENTS OF STUDY.—The cases of
- 11 chronic pain with respect to which the study required in
- 12 subsection (a) is conducted shall include reflex sympathetic
- 13 dystrophy syndrome, temporomandibular joint disorder,
- 14 post-herpetic neuropathy, painful diabetic neuropathy,
- 15 phantom pain, and post-stroke pain.
- 16 (c) Report.—Not later than 2 years after the date of
- 17 the enactment of this Act, the Director shall complete the
- 18 study required in subsection (a) and submit to the the Com-
- 19 mittee on Energy and Commerce of the House of Represent-
- 20 atives, and to the Committee on Labor and Human Re-
- 21 sources of the Senate, a report describing the findings made
- 22 as a result of the study.
- 23 **SEC. 1908. BACK INJURIES.**
- 24 (a) In General.—The Director of the National Insti-
- 25 tutes of Health, acting through the appropriate national re-

1	search institute, shall conduct a study of back injuries, with
2	consideration of the following:
3	(1) Accurate diagnosis, and the appropriate form
4	of treatment.
5	(2) Providing for return to employment as soon
6	as is practicable.
7	(3) Minimizing the probability of recurrence.
8	(4) A comparison of conventional treatments and
9	alternative treatments.
10	(5) Costs to the health care system.
11	(6) Costs to the economy generally.
12	(b) Report.—Not later than 1 year after the date of
13	the enactment of this Act, the Director of the National Insti-
14	tute of Health shall complete the study required in sub-
15	section (a) and submit to the Committee on Energy and
16	Commerce of the House of Representatives, and to the Com-
17	mittee on Labor and Human Resources of the Senate, a
18	report describing the findings made as a result of the study

1	TITLE XX—MISCELLANEOUS
2	PROVISIONS
3	SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RE-
4	SEARCH SERVICE IN HONOR OF SILVIO O.
5	CONTE; LIMITATION ON NUMBER OF MEM-
6	BERS.
7	(a) In General.—Section 228(a) of the Public Health
8	Service Act (42 U.S.C. 237(a)), as added by section 304
9	of Public Law 101–509, is amended to read as follows:
10	"(a)(1) There shall be in the Public Health Service a
11	Silvio O. Conte Senior Biomedical Research Service, not
12	to exceed 750 members.
13	"(2) The authority established in paragraph (1) re-
14	garding the number of members in the Silvio O. Conte Sen-
15	ior Biomedical Research Service is in addition to any au-
16	thority established regarding the number of members in the
17	commissioned Regular Corps, in the Reserve Corps, and in
18	the Senior Executive Service. Such paragraph may not be
19	construed to require that the number of members in the com-
20	missioned Regular Corps, in the Reserve Corps, or in the
21	Senior Executive Service be reduced to offset the number
22	of members serving in the Silvio O. Conte Senior Bio-
23	medical Research Service (hereafter in this section referred
24	to as the 'Service'). ''.

1	(b) Conforming Amendment.—Section 228 of the
2	Public Health Service Act (42 U.S.C. 237), as added by
3	section 304 of Public Law 101–509, is amended in the head-
4	ing for the section by amending the heading to read as fol-
5	lows:
6	"SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH
7	SERVICE''.
8	SEC. 2002. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE
9	FOR RESEARCH.
10	Not later than 18 months after the date of the enact-
11	ment of this Act, the Secretary of Health and Human Serv-
12	ices, acting through the Director of the National Institutes
13	of Health, shall present to the Congress a master plan to
14	provide for the replacement or refurbishment of less than
15	adequate buildings, utility equipment and distribution sys-
16	tems (including the resources that provide electrical and
17	other utilities, chilled water, air handling, and other serv-
18	ices that the Secretary, acting through the Director, deems
19	necessary), roads, walkways, parking areas, and grounds
20	that underpin the laboratory and clinical facilities of the
21	National Institutes of Health. Such plan may make rec-
22	ommendations for the undertaking of new projects that are
23	consistent with the objectives of this section, such as encir-
24	cling the National Institutes of Health Federal enclave with
25	an adequate chilled water conduit.

1	SEC. 2003. CERTAIN AUTHORIZATION OF APPROPRIATIONS.
2	Section 399L(a) of the Public Health Service Act (42
3	U.S.C. 280e-4(a)), as added by Public Law 102-515 (106
4	Stat. 3376), is amended—
5	(1) in the first sentence, by striking "the Sec-
6	retary" and all that follows and inserting the follow-
7	ing: "there are authorized to be appropriated
8	\$30,000,000 for fiscal year 1994, and such sums as
9	may be necessary for each of the fiscal years 1995
10	through 1996.''; and
11	(2) in the second sentence, by striking "Out of
12	any amounts used" and inserting "Of the amounts
13	appropriated under the preceding sentence".
14	SEC. 2004. BUY-AMERICAN PROVISIONS.
15	No funds appropriated pursuant to this Act may be
16	used to fund a grant or contract unless the recipient agrees
17	that substantially all goods and services acquired with such
18	grant or contract assistance will be produced in the United
19	States.
20	TITLE XXI—EFFECTIVE DATES
21	SEC. 2101. EFFECTIVE DATES.
22	Subject to section 165, this Act and the amendments
23	made by this Act take effect upon the date of the enactment
24	of this Act.

1 SEC. 2005. PROHIBITION AGAINST FURTHER FUNDING FOR

- 2 **PROJECT ARIES.**
- 3 For fiscal year 1994 and each subsequent fiscal year,
- 4 the project administered by the University of Washington
- 5 at Seattle and known as Project Aries may not receive any
- 6 funding from any agency of the National Institutes of
- 7 Health, other than payments under awards made for fiscal
- 8 year 1993 or prior fiscal years.

Attest:

Clerk.

- S 1 EAH——2
- S 1 EAH——3
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